

EXPRESS MAIL LABEL NO.: EV980042953US
DATE: May 2, 2007

PATENT
TEVNHC 3.3-083

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	:	
Barney et al.	:	
	:	Group Art Unit: Not Yet Assigned
U.S. Application o.: 10/574,386	:	
	:	Confirmation No.: 2232
International Application No.	:	
PCT/US2004/032160	:	
	:	Examiner: Not Yet Assigned
International Filing Date: October 2, 2004	:	
	:	Date: May 2, 2007
For: DRY POWDER INHALATION	:	
APPARATUS	:	

MS PCT
Commissioner for Patents
Office of PCT Legal Admin.
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C.
371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) AND
PETITION UNDER 37 C.F.R. § 1.47(a)

Sir:

This is in response to the Notification Of Missing Requirements under 35 U.S.C. 371 In The United States Designated/Elected Office (DO/EO/US), dated October 2, 2006. A copy of the Notification is enclosed.

The present patent application names Brian Barney, David O'Leary and Rachel Striebig as co-inventors. A statutory Declaration under 37 C.F.R. § 1.63, executed by Brian Barney, is enclosed herewith. In accordance with MPEP § 409.03(a), the Declaration contains a signature block for all three inventors. Co-Inventors O'Leary and Striebig have not executed the enclosed declaration. Thus, Applicants respectfully submit the following information and documentation in support of this Petition Under 37 CFR § 1.47(a).

Pursuant to 37 C.F.R. § 1.47(a), the last known address of the non-signing inventors is as follows:

David O'Leary, 25 Newburgh Road, Little Thurrock Grays, Essex, RM17 6UG, United Kingdom;

Rachel Striebig, Flat 4, Cyna Court, Cambridge Road, London E11 2PW, United Kingdom.

The enclosed Exhibit A is an Affidavit of Samantha Claire Radley, Patent Administrator for Norton Healthcare Limited (the assignee of the present patent application), which states the facts relating to the diligent attempts she has made to obtain the signature of inventor David O'Leary. In her Affidavit, Ms. Radley explains that on two separate occasions, she mailed to Mr. O'Leary, at his last known address, the application papers as filed, including the specification, drawings and claims. The Affidavit also sets forth the attempts she has made to locate Mr. O'Leary, including internet searches, re-mailing of the application papers, and contacts with the Human Resources department of the assignee, Norton Healthcare Limited. All attempts to locate and obtain the signature of Mr. O'Leary failed.

The enclosed Exhibit B is another Affidavit of Samantha Claire Radley, which states the facts relating to the diligent attempts she has made to obtain the signature of inventor Rachel Striebig. In her Affidavit, Ms. Radley explains that on two separate occasions, she mailed to Ms. Striebig, at her last known address, the application papers as filed, including the specification, drawings and claims. The Affidavit also sets forth the attempts made she made to locate Ms. Striebig, including internet searches, re-mailing of the application papers, and attempts to contact her by telephone. All attempts to locate and obtain the signature of Ms. Striebig failed.

The two Affidavits of Samantha Claire Radley are believed to establish that diligent efforts were made to contact the inventors and obtain their signatures on the Declaration.

It is respectfully submitted that the present Response and Petition, together with the documentation enclosed herewith, meet the requirements of 37 C.F.R. § 1.47(a). Acceptance of the captioned patent application under 37 C.F.R. § 1.47 is respectfully requested.

Further enclosed herewith is a Petition for extension of time to respond to the Notification Of Missing Requirements under 35 U.S.C. 371 In The United States Designated/Elected Office (DO/EO/US).

Application No. 10/574,386

The Commissioner is hereby authorized to charge to our Deposit Account No. 12-1095: the petition fee pursuant to Rule 1.17(h) for the present Rule 47(a) Petition (\$130.00). In the event that any other fees are due in connection with this present petition, the Commissioner is hereby authorized to charge Deposit Account No. 12-1095 therefor.

Respectfully submitted,

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP



SHAWN P. FOLEY
Reg. No. 33,071

600 South Avenue West
Westfield, New Jersey 07090
Telephone: (908) 654-5000
Facsimile: (908) 654-7866

760833_1.DOC



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/574.386	Brian Barney	TEVA33001

000530
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

02 Dec 2006

INTERNATIONAL APPLICATION NO.	
PCT/US04/32160	
I.A. FILING DATE	PRIORITY DATE
10/02/2004	

CONFIRMATION NO. 2232
371 FORMALITIES LETTER



QC000000020661539

Date Mailed: 10/02/2006

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- **Copy of the International Application filed on 03/31/2006**
- **Preliminary Amendments filed on 03/31/2006**
- **U.S. Basic National Fees filed on 03/31/2006**
- **Priority Documents filed on 03/31/2006**

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

Additionally the following defects have been observed:

- **The International Search Report has not be supplied, the Search Fee has been adjusted to reflect this omission.**

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

CHARITTA A BURT

Telephone: (703) 308-9140 EXT 207

PART 2 - OFFICE COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/574,386	PCT/US04/32160	TEVA33001

FORM PCT/DO/EO/905 (371 Formalities Notice)

Filed on behalf of Norton Healthcare Limited
Deponent: S. C. Radley
First Affidavit of the Deponent
Date of Swearing: 24 April 2007
Exhibits: SR1-5

IN THE MATTER of United States Patent Application Number 10/574,386

AFFIDAVIT OF SAMANTHA CLAIRE RADLEY

I, SAMANTHA CLAIRE RADLEY, of 79a Gellatly Road, London SE14 5TU
Patent Administrator, MAKE OATH and say as follows:

1. I am a Patent Administrator for Norton Healthcare Limited ("Norton") and I make this affidavit in support of Norton's United States patent application number 10/574,386 entitled "Dry Powder Inhalation Apparatus". In so far as the content of this affidavit is within my personal knowledge it is true, and so far as it is not within my personal knowledge it is true to the best of my knowledge information and belief.
2. On 3 August 2006, I sent a bundle of documents consisting of a Declaration for Utility or Design Patent Application, a copy of US Patent Application No. 10/574,386 and an Assignment of Utility Application form by DHL courier to the address for David O'Leary as shown on the patent application. The DHL package was returned to me with "Not known at this address. Please return to sender" written on it. I present the bundle of documents, envelope used to send the documents and the returned DHL package cover as exhibit SR1.
3. On 5th January 2007, I sent the same documentation to the same address and it was returned to me. The contents of the DHL courier package were identical to those of exhibit SR1. A copy of the covering letter is presented as exhibit SR2.
4. On 1st March 2007, I interrogated an internet based website called 192.com, a database that contains current United Kingdom electoral roll details and residential telephone numbers for residents in the United Kingdom, with the search term 'David O'Leary'. The web site returned "Sorry, no matched results" in response to the query for David O'Leary. The web page printout is presented as exhibit SR3
5. On 1st March 2007, I interrogated an internet site called "The Phone Book" which holds residential telephone numbers for residents in the United Kingdom for "D O'Leary in Grays, Essex". The web site returned "The person could not be found", a printout of that search is presented as exhibit SR4.

6. I would normally expect that, if a person was resident in the United Kingdom, I would be able to find their details using either of these websites. The fact that both attempted were unsuccessful leads me to believe that David O'Leary cannot be found.

7. On 6th March 2007, I contacted Jaz Ghick, HR Advisor for Norton's Human Resources Department and asked whether Norton Healthcare had received any request for a reference for David O'Leary from a later employer in order to allow me to contact that employer for his current contact details. Jaz Ghick informed me that there had been no such request. The email exchange is presented as exhibit SR5.

8. It is my belief that I cannot contact David O'Leary

Sworn at... BLOOMSBURY
HOUSE, 62-65 BLOOMSBURY
PLACE, LONDON WC2N 4LP

this 24 day of
APRIL 2007



Signature of Deponent making the Affidavit

Before me,


AYESHA BRAMWELL
PRACTISING SOLICITOR AT
Shepherd and Wedderburn LLP
Condor House
10 St. Paul's Churchyard
LONDON
EC4M 8AL



Signature of Authorised Witness

IN THE MATTER of United States Patent Application Number 10/574,386

EXHIBIT SR1 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY



SAMANTHA CLAIRE RADLEY



PRACTISING SOLICITOR



Subsidiary of **IVAX** Corporation

Mr David O Leary
25 Newburgh Road
Little Thurrock
Grays
Essex RM17 6UG

Albert Basin, Royal Docks
London E16 2QJ

Telephone 08705 02 03 04
Fax 08705 32 33 34

3rd August 2006

RESENT 5/1/07.

Dear David,

RE: US National Phase of PCT/2004/032160 for
DRY POWDER INHALATION APPARATUS
in the name of Norton Healthcare Limited

Please find enclosed a declaration for use in the prosecution of the above United States patent application by Norton Healthcare Limited. Please can you sign and date the declaration where indicated.

There is also an Assignment form that should be witnessed by someone who knows you at the time of your signing. Please can you sign the assignment in the presence of such a witness who should then also sign the assignment to show that your signature is indeed your true signature.

Please return the forms in the stamped, addressed envelope provided as quickly as possible.

Thanks for your help.

Best regards.

Yours sincerely

David W. Cottam Ph.D.
Intellectual Property Counsel
Norton Healthcare Limited

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION				ADDITIONAL INVENTOR(S) Supplemental Sheet		Page <u>1</u> of <u>1</u>	
-------------	--	--	--	--	--	---------------------------	--

Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle (if any))				Family Name or Surname			
Rachel				Striebig			
Inventor's Signature				Date			
Residence: City		State		Country		Citizenship	
London				United Kingdom		United Kingdom	
Mailing Address: 28A Loampit Hill, Lewisham							
City		State		Zip		Country	
London				SE13 7SW		United Kingdom	

Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle (if any))				Family Name or Surname			
Inventor's Signature				Date			
Residence: City		State		Country		Citizenship	
Mailing Address:							
City		State		Zip		Country	

Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle (if any))				Family Name or Surname			
Inventor's Signature				Date			
Residence: City		State		Country		Citizenship	
Mailing Address:							
City		State		Zip		Country	

Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle (if any))				Family Name or Surname			
Inventor's Signature				Date			
Residence: City		State		Country		Citizenship	
Mailing Address:							
City		State		Zip		Country	

Please type a plus sign (+) inside this box → ☐

PTO/SB/01 (03-01)

Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63) <input type="checkbox"/> Declaration Submitted with Initial Filing OR <input checked="" type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)	Attorney Docket Number	TEVA 3.3-083
	First Named Inventor	Brian Barney
	COMPLETE IF KNOWN	
	Application Number	Not Yet Assigned
	Filing Date	Concurrently Herewith
	Group Art Unit	N/A
	Examiner Name	Not Yet Assigned

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am an original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

DRY POWDER INHALATION APPARATUS

(Title of the Invention)

the specification of which

☐ is attached hereto
OR

☒ was filed on (MM/DD/YYYY) 10/02/2004 as United States Application Number or PCT International

Application No. PCT/US2004/032160 and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
0323085.1	GB	10/02/2003	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

Please type a plus sign (+) inside this box ☐

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			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle (if any))				Family Name or Surname			
Rachel				Striebig			
Inventor's Signature				Date			
Residence: City		State		Country		Citizenship	
London				United Kingdom		United Kingdom	
Mailing Address:				28A Loampit Hill, Lewisham			
City		State		Zip		Country	
London				SE13 7SW		United Kingdom	

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Inventor's Signature				Date			
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Inventor's Signature				Date			
Residence: City		State		Country		Citizenship	
Mailing Address:							
City		State		Zip		Country	

Please type a plus sign (+) inside this box → ☐

PTO/SB/01 (03-01)
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OR

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			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

Please type a plus sign (+) inside this box ☐

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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DECLARATION — Utility or Design Patent Application

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: Customer Number 000530

Direct all correspondence to:		<input checked="" type="checkbox"/> Customer Number or Bar Code Label	000530		OR <input type="checkbox"/> Correspondence address below
Name					
Address					
City		State		ZIP	
Country		Telephone		Email	
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.					
NAME OF SOLE OR FIRST INVENTOR:				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))			Family Name or Surname		
Brian			Barney		
Inventor's Signature				Date	
Residence: City		State		Country	
Essex				United Kingdom	
Mailing Address:		50 Stortford Road, Great Dunmow			
City		State		Country	
Essex				United Kingdom	
ZIP		CM6 1DN			
NAME OF SECOND INVENTOR:				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))			Family Name or Surname		
David			O'Leary		
Inventor's Signature				Date	
Residence: City		State		Country	
Essex				United Kingdom	
Mailing Address:		25 Newburgh Road, Little Thurrock Grays			
City		State		Country	
Essex				United Kingdom	
ZIP		RM17 6UG			
<input checked="" type="checkbox"/> Additional inventors are being named on the <u>1</u> supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.					

L.D-537A

Please type a plus sign (+) inside this box



PTO/SB/01 (03-01)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION — Utility or Design Patent Application

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: Customer Number 000530

Direct all correspondence to:		<input checked="" type="checkbox"/> Customer Number or Bar Code Label	000530	OR <input type="checkbox"/> Correspondence address below
Name				
Address				
City		State		ZIP
Country		Telephone		Email
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.				
NAME OF SOLE OR FIRST INVENTOR:			<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any])		Brian		Family Name or Surname
Inventor's Signature		Barney		Date
Residence: City		United Kingdom		Citizenship
Mailing Address:		50 Stortford Road, Great Dunmow		
City		State		Country
Essex		CM6 1DN		United Kingdom
NAME OF SECOND INVENTOR:			<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any])		David		Family Name or Surname
Inventor's Signature		O'Leary		Date
Residence: City		United Kingdom		Citizenship
Mailing Address:		25 Newburgh Road, Little Thurrock Grays		
City		State		Country
Essex		RM17 6UG		United Kingdom
<input checked="" type="checkbox"/> Additional inventors are being named on the <u>1</u> supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.				

L.D-537A

Please type a plus sign (+) inside this box ☐

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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DECLARATION — Utility or Design Patent Application

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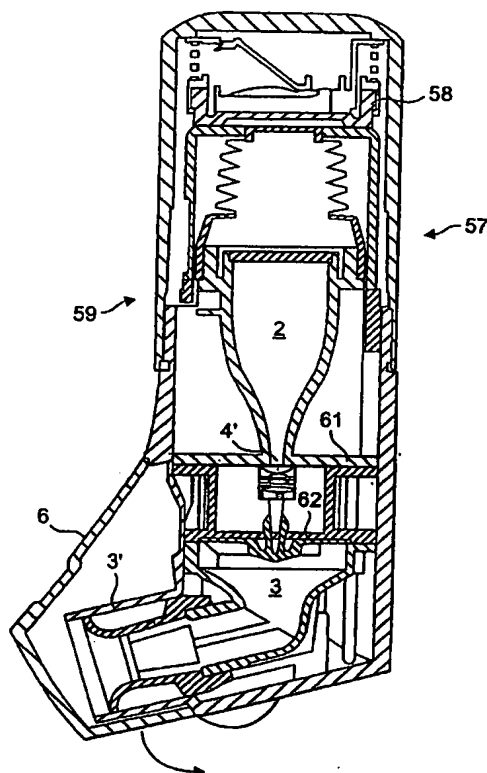
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(54) Title: **DRY POWDER INHALATION APPARATUS**



(57) Abstract: The invention relates to dry powder inhalation apparatus usually operable by breath of a user which provides for controlled and smooth transfer of medicament during multiple actuations by a user. A mechanism of the apparatus for achieving this controlled and smooth transfer includes a device (4) normally held adjacent a reservoir for receiving medicament in a cup or receptacle (15) and which is generally movable transversely of a longitudinal axis of the apparatus to delivery channels of the apparatus. This bodily shifting of the device (4) is achieved by a yoke acting on an abutment (16) thereof. Spillage of medicament in the apparatus is avoided.



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DRY POWDER INHALATION APPARATUS

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(Attorney Docket: NHC0083-UNK)

BACKGROUND OF THE INVENTION

[0001] The invention relates to dry powder inhalation apparatus. This apparatus administers a dry powder medicament in a desired pre-determined dose to a user of the apparatus who actuates the apparatus manually and then breathe in the predetermined dose, or, on taking a breath, would automatically actuate the device for breathing in the predetermined dose of medicament. Breath actuation is typically used to dispense the desired dose of medicament into the lungs of the patient. The medicament is carried in air during inhalation so that fine particles are carried into the lungs and heavier particles are retained in the buccal cavity.

[0002] Typically such an apparatus includes a reservoir for containing the medicament in dry powdered form. The reservoir contains medicament for a particular number of doses. The doses are metered from the reservoir one dose at a time on actuation by a user. The apparatus also includes an air inlet or inlets for taking up or entraining the medicament for passage along airways through a mouthpiece of the apparatus and into the lungs of the user when the user takes a breath.

[0003] The amounts of medicament in a particular dose are small and received from the reservoir in a device having a receptacle or cup for receiving a metered dose of medicament. The device then shifted bodily in order to transfer the metered dose to the air channels. The body of the device seals off a discharge outlet from the reservoir during this transfer motion.

[0004] In known apparatus, a mechanism transfers a slide carrier assembly carrying a metered dose by releasing the slide carrier off the end of a lower ledge of a yoke. A yoke lower moves as a trigger is rotated by a mouthpiece cover opening. The trigger has two drop zones. The first of these is used to generate sudden movement of the yoke lower to compress a bellows for metering. The second drop zone is also sudden, and it is during this zone that the yoke lower releases the slide carrier. The transfer spring forces the slide carrier across a

channel between a hopper upper and a hopper lower components. When the slide carrier hits the side wall of the hopper upper the slide carrier stops abruptly.

[0005] However, even though a relatively small amount of powder is being dispensed, the powder making up each dose can be compacted which can cause more than the prescribed dosage to be received in the cup.

[0006] Moreover, even if there is no compaction, the medicament can be spilled from the cup on transfer. Consequently, although there is a collection well for receiving spilled medicament, the required desired dosage may not be administered when the user takes a breath.

[0007] Both disadvantages of compaction and spillage result from the way in which the device is transferred from the discharge outlet of the reservoir to the position for passage of the medicament into the air channels.

[0008] Accordingly, the present invention mitigates these disadvantages.

SUMMARY OF THE INVENTION

[0009] According to the present invention, there is provided dry powder inhalation apparatus, comprising a reservoir for medicament, a mouthpiece for insertion in the mouth of a user for inhalation of a predetermined dose of medicament, a delivery channel between a discharge outlet of the reservoir and the mouthpiece for delivering said predetermined dose of medicament, a device normally held adjacent the reservoir for receiving said predetermined dose of medicament from said discharge outlet and transferring it to the delivery channel, and a mechanism adapted to release the device and permit controlled movement thereof to the delivery channel for said delivery.

[0010] It will be understood that in using the invention it is possible to provide for controlled, smooth transfer of a required dose of medicament in a two-stage operation. Movement of the device is interrupted after charging with medicament for subsequent controlled movement to the position for passage of the medicament into air channel(s) forming the discharge channels.

[0011] The device may comprise a cup for receiving said dose and a longitudinally slidable body mounting said cup, the mechanism comprising abutment means which is movable to release the device for movement to the delivery channel.

[0012] The abutment means may preferably be bodily movable by an actuation means. This provides for positive operation and actuation.

[0013] The abutment means may also comprise a resilient member which is flexible out of the path of the device. This again provides a positive operation and actuation, particularly when the resilient member may comprise a one piece member of substantially J- or U-configuration, one limb of which is movable for releasing the device.

[0014] The movable limb may have a finger-operable tab projecting from a housing apparatus, and the tab may have indicia indicating the direction of flexing of the limb for release of the device.

[0015] The actuation means may comprise a resiliently mountable slidable member which has a tab projecting through a bore of a body of the apparatus for releasing the device. This also provides for positive operation and actuation, the slidable member preferably having indicia which can be read through the bore for indicating the position of the device.

The indicia may suitably comprise a colour code indicia.

[0016] The actuation means may further comprise a resiliently and pivotably mounted detent means which is shiftable bodily about its pivot axis to release the device.

[0017] Suitably, the detent means may have a finger grippable projection which projects therefrom and through a slot in the body of the apparatus for bodily shifting of the detent when the projection is moved along the slot.

[0018] The actuating means may further comprise a resiliently mounted plunger means which has one end projecting through a bore in a body of the device and an opposite end adapted to engage the device for shifting same bodily to said delivery channel.

[0019] The plunger means may suitably have a substantially cylindrical body member connecting the one end and the opposite end, and the opposite end may be enlarged relative to the body member.

[0020] There may be a relatively soft cushion member of the opposite end for contacting the device. This provides for a cushioned, controlled motion of the device.

- [0021] The actuation means may comprise an electrical, electronic or electro-mechanical means.
- [0022] The actuation means may comprise a solenoid means actuated by a switch device for actuation of the device. Suitably, the switch device may be operable manually by a user, or alternatively the switch device may be operable by inhalation of a breath by a user. In either mode, a positive operation of the device can be achieved.
- [0023] There may be a power source for the electrical, electronic or electro-mechanical means.
- [0024] There may be a cover for an end of the discharge channel at the mouthpiece, and the cover may be movable between a position covering the discharge channel and a position for discharging said dose, whereby to allow actuation of the mechanism.
- [0025] The cover may suitably comprise a relatively rigid disc carried by opposed arms which at an end thereof opposite the disc mount a cam which has a profile for allowing movement of a cam follower in a direction away from the device whereby to allow operation of the actuation means for bodily movement of the abutment means.
- [0026] The disc in its first mentioned position may be housed within a guard of the apparatus, which guard is pivotably mounted for access to the disc.
- [0027] There may be a yoke member which is shiftable bodily towards and away from the mouthpiece and mounting limbs, one of which has a cam follower for following a cam which is rotatable for actuation of the yoke member which carries the actuation means in the form of a ramp up which a part at least of the device can travel for controlled movement thereof towards the delivery channel. This again provides a positive operation, particularly when the actuation means comprises a return element for returning the device to the charging position.
- [0028] Such a return element may suitably comprise an inclined ledge down which the part travels to said discharge outlet.
- [0029] The apparatus may be a breath actuable apparatus.
- [0030] The mechanism may be between opposed spaced walls of the reservoir and may have a member which may be retractable on a user taking a breath on the mouthpiece.
- [0031] The mechanism may comprise cooperating rotatable means one of which has a detent for engaging the device and the other of which is operable to maintain the detent in

engagement with the device and to allow rotation of the one means to release the detent and device.

[0032] The mechanism may further comprise a stop member, retractable as a user taking a breath on the mouthpiece, and adapted to release the other rotatable means and the detent.

[0033] The rotatable means may comprise cam or gear means.

[0034] The stop member may suitably comprise an elongate mounted member which is biased to engage the other rotatable means and a flap valve which is operable to allow air into a space between said opposed walls to equalise air pressure inside and outside the space and bias the elongate members to operate the cam or gear means.

[0035] The device may be mounted under pressure resilient means, suitably spring means.

[0036] There may also be damper means for damping movement of the device.

[0037] Embodiments of the apparatus according to the invention are hereinafter described, by way of example, with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0038] Fig. 1 shows a perspective view of a typical dry powder inhalation apparatus;

[0039] Fig. 2 shows an exploded perspective view of a typical dry powder inhalation apparatus like that of Fig. 1;

[0040] Fig. 3 shows to a much enlarged scale a perspective view of an embodiment of device for dispensing a desired dose of medicament according to the invention;

[0041] Fig. 4 shows to a much enlarged scale a perspective view of a second embodiment of device for dispensing a desired dose of medicament according to the invention;

[0042] Figs. 5A and 5B shows respectively two operative positions of a third embodiment of apparatus according to the invention;

[0043] Fig. 6 shows a plan view of a fourth embodiment of apparatus according to the invention;

[0044] Fig. 7 shows schematically a fifth embodiment of apparatus according to the invention;

[0045] Fig. 8 shows schematically a perspective view of a further embodiment of apparatus according to the invention;

[0046] Fig. 9 shows schematically a further embodiment of inhalation device according to the invention;

[0047] Fig. 10 shows in (a) – (d) different positions of yet further apparatus embodying the invention;

[0048] Fig. 11 shows part of actuating mechanism of the embodiment of Fig. 10;

[0049] Fig. 12 shows schematically a breath operated dry powder inhalation device;

[0050] Fig. 13 shows part of the device of Fig. 12 shown in an embodiment according to the invention;

[0051] Fig. 14 shows a way of mounting the device of the apparatus of the previously described embodiment; and

[0052] Fig. 15 shows schematically a production model apparatus similar to that shown in Fig. 10, however in this embodiment a cam of the apparatus is solid.

DETAILED DESCRIPTION OF THE INVENTION

[0053] Referring to the drawings (see for example Figs. 1, 2, 3, 9), and in which like parts are referred to by like numerals where feasible, there is shown dry powder inhalation apparatus 1, comprising a reservoir 2 for medicament, a mouthpiece 3' for insertion in the mouth of a user for inhalation of a predetermined dose of a medicament, a delivery channel 3 between a discharge outlet 4' of the reservoir 2 and the mouthpiece for delivering said predetermined dose of medicament, a device 4 normally held adjacent the reservoir for receiving a predetermined dose of medicament from said discharge outlet and transferring it to the delivery channel, and a mechanism 5 adapted to release the device 4 and permit controlled movement thereof to the delivery channel for said delivery.

[0054] Fig. 1 shows the general outline of the inhalation apparatus 1 from in front there being a pivotable cover 6 at the bottom (and as used) of a body 7 of the device.

[0055] As shown in Fig. 2, the housing or body 7 of the apparatus 1 includes a cap 8, an internal spring 9, a yoke 10, a bellows 11, an actuating mechanism including a further yoke 12, a counter 13, viewable in the base 14 of the body 7 mounting the mouthpiece cover 6.

[0056] The mechanism 5 (Fig. 3. and Fig. 12 for example) includes the device 4 which is generally movable transversely of a longitudinal axis of the apparatus 1 for receiving in a cup or receptacle 15 a metered dose of powdered medicament which is then transferred by the shifting of the device 4 to the discharge channels or airways 3 which when a patient breathes in on sucking on the mouthpiece 3', removes the powdered metered dose from the cup or receptacle 15 so that it is entrained in the air and passes through the mouthpiece 3' into the lungs and mouth of the user. Charging of the cup or receptacle 15 with medicament is effected from a discharge outlet 4' (Fig. 12) of the reservoir 2 by the bellows 11 on movement of the yoke 10 in a position towards the mouthpiece 3', there being a part in the form of a shoulder, boss or abutment 16 of the device 4, for shifting the device longitudinally bodily from the discharge outlet 4' to the air delivery channel 3.

[0057] In order to provide a smooth operation, there is positioned at the fore end of the device 4 an abutment 5 which has physically to be moved bodily out of the way of the device and, as shown in Fig. 3, this abutment is of L-shape which on movement by finger pressure on an end 17 shifts the abutment 5 so that an upstanding integral part 18 thereof is clear of the adjacent end of the device 4 so that the device 4 can then be moved smoothly to the discharge position under pressure of a spring (which is not shown).

[0058] Fig. 4 shows a further embodiment in which the abutment comprises a resilient member 19 in the form of in the embodiment shown a J-shaped plastic spring-like member, the lower or shorter limb 20 of which is secured in the body 7 of the apparatus 1 and the upper limb 21 of which is able to be flexed out of the path of the device 4 on movement of a tab 22 downwardly as shown by the indicia 'A' in the form of an arrow on the outside surface thereof.

[0059] When the underside of the longer limb 21 meets the upper surface of the lower limb 20 and therefore cannot be lowered further, the user knows that there is a positive "stop", and the desired medicament is available for inhalation.

[0060] Turning now to Figs. 5A and 5B, the mechanism 5 includes a pivotable stop 23. The stop 23 is of generally L-shape and is mounted for pivotable movement on an axis 24 under spring pressure 25 which tends to bias it towards a position obstructing movement of the device 4.

[0061] The pivot 24 is mounted in holes 26 in facing members of upper and lower flanges 27, 28 of the reservoir or hopper 2.

[0062] There is a projection 29 from one limb of the abutment member 23, the projection 29 being accessible manually through an orifice 30 in a wall of the body 7 by a user who on turning the projection 29 in the direction shown by the arrow 31, releases the device 4 for smooth but positive motion to the discharge position, the projection 29 when it meets a blind wall of the orifice 30 effectively informing the user that the desired dosage of medicament is again available for inhalation.

[0063] Fig. 6 shows a yet further embodiment in which there is a slidable ring-shaped member 32 which is mounted under pressure of a spring 33 to be biased to a position in which a projection 34 of the ring 32 interferes with the motion of the device 4. The ring member 32 also includes a button 35 which projects through an opening or orifice 36 in a wall 7 of a body of the apparatus 1.

[0064] The ring 32 includes indicia 37 either in lettering or in colour, for example in red and green showing when the device 4 is not ready for dispensation (red) or is ready for dispensation and thus inhalation (green).

[0065] The user can read this indicia when the button 35 is pushed under finger or thumb pressure from left to right as shown by the arrow 'X' in Fig. 6, thereby releasing the device 4 and thus making the medicament ready for inhalation.

[0066] Turning now to Fig. 7, an embodiment is shown in which a button or plunger 38 mounted in a wall 7 of the apparatus 1 under spring 39 pressure is biased away from contact with an abutment of the device 4, but on actuation of a head 40 of the plunger inwardly the opposite end 41 thereof which is enlarged relative to a cylindrical body 42 of the plunger contacts the device 4 and shifts it bodily and smoothly to the left as viewed ready for discharge to the air channels, on inhalation.

[0067] Release of the button 38 retracts the plunger so that the device 4 itself can return for further charging, the device as in all embodiments, being mounted under spring pressure which biases it towards the charging position. The enlarged opposite end 41 of the plunger 38 may include a cushion (not shown) for providing a cushioned contact of the plunger with the device 4.

[0068] Fig. 8 shows a yet further embodiment in which there is an actuator 43 such as an electrical, electronic or electro-mechanical actuator having an extensible actuating member such as a piston rod 44 which on operation of the actuator 43 extends to push the abutment 45 of the

mechanism out of the path of the device 4, for discharge as before. The actuator 43 in this embodiment includes a switch 46, and a power source 47 such as a battery. The switch 46 may be operated manually, or automatically when a user takes a breath.

[0069] Turning now to Fig. 9, there is shown an embodiment in which the mouthpiece 3' is normally covered by a flap or disc 48 which is mounted on two arms 49 at the end of which opposite the flap or disc 48 there is a cam device 50 which operates the operating mechanism by allowing a cam follower 51 to follow the shape of the cam 50 thereby to allow the cup of the device to be charged and then for a mechanism like that labelled (5) in Fig. 3 but not shown in Fig. 9, to allow for smooth transfer of the device 4 for discharge of the inhalation dose with the medicament as described hereinbefore.

[0070] The flap, or cover 48, carries externally an indicia 52 such as an arrow to indicate to a user the direction in which the flap should be pivoted to effect operation and to expose the mouthpiece 3' for inhalation, the cover in the closed position of the mouthpiece being itself closed by a pivotable external cover 6.

[0071] Turning now to Figs. 10 and 11, there is shown schematically a mechanism in which the part 16 of the device 4 is initially in the rest position shown in (a) against a ratchet part of a yoke 12 which has a lower cam 53 and which is resilient and profiled in a direction orthogonal to that as viewed, as by being convex. When that yoke 12 is actuated and pulled down for charging the cup 15 with the desired dosage of medicament, the part 16 rides up the ratchet as shown at (b) and then, to effect transfer, it moves gently and smoothly upwardly along a ramp 54 owing to the resilience and profile of the ratchet, as shown at (c). On return of the ratchet upwardly, arrow 'Y', the part 16 of the device 4 is engaged by a downward sloping element 55 (left to right as viewed in (b)), and, in order to accommodate upward movement of the ratchet, the part 16 of the device 4 moves down the slope or return element 55 thereby returning the device 4 to the position for charging.

[0072] Fig. 15 shows schematically a production model of apparatus embodying the invention. In Fig. 15, there is shown a schematically mechanism in which the part 16 of Fig. 10 of the device 4 shown as 110 in Fig. 15, is initially in a rest position, 'position 1', against a cam part of yoke 12 which has a lower cam 53 and which is resilient and profiled in a direction orthogonal to that as viewed, as being convex. When that yoke 12 is actuated and pulled down for charging the cup 15 with the desired dosage of medicament, the part 110 rides up ramp 106

of the cam, shown in 'position 2', and then, to effect transfer, it moves gently and smoothly upwardly along a ramp 112 to the inhalation position at 'position3'. On return of the yoke 12 upwardly, arrow Y, the part 110 of the device 4 returns along the ramp 112 of the cam shown in 'position 4', thereby returning the device 4 to the position for charging.

[0073] This action is exemplified in Fig. 11 where the lower end of the yoke 12, adjacent the mouthpiece, follows a single cam follower 56 of a cam which is rotatable by the mouthpiece 6, or cover 52 (Fig. 9).

[0074] Fig. 12 shows a breath actuated dry powder inhalation apparatus 57 in which there is a force handling unit 58 on top of a lower body part 59 of the apparatus 57, the device 4 being actuatable only when the patient takes a breath as known from previous breath operated examples such as that marketed under the trade mark Easi-Breathe. In this embodiment when the patient inhales a mechanism 60 shown in Fig. 13 is operative to provide for dispensation of the required dose of medicament. In this embodiment, between the upper 61 and lower 62 flanges of the reservoir 2, there is a double cam or gear arrangement, the first or upper 63 one of which as viewed has an extension 64 which engages the device 4 to hold it in the charging position, there being an elongate actuating member 65 which is operative to rotate the cam or gear 67 whereby it in turn can rotate the cam or gear 63 out of contact with the device 4 thereby allowing the device 4 to move for inhalation.

[0075] The elongate member 65 is mounted under pressure of a spring 66 there being a valve and seal arrangement 68 operable when a patient breathes on the mouthpiece to lift a flap valve 69 thereof, thereby allowing atmospheric air to enter a space 70 defined between the upper and lower flanges 61, 62 of the reservoir and between a wall 71 spacing those two flanges apart so that the spring 66, under the pressure of which the elongate member is mounted, is retracted thereby, the air pressure either side of the wall being equalised.

[0076] Turning now to Fig. 14, this shows schematically the device 4 mounted underneath the charging opening 4' from the reservoir 2 so that the cup 15 is aligned with that charging opening. The device 4 is mounted under pressure of a spring to return to the position shown, there is also a damper device 72 such as a dash pot which on operation of the mechanism to move the device longitudinally bodily to the left as shown by the arrow 'R', is active to provide a smooth, controlled passage from the charging opening to the air channel, for inhalation of the desired predetermined dose of powdered medicament.

[0077] All the embodiments herein described with reference to the accompanying drawings describe dry powder inhalation apparatus which provides for charging of a cup of a discharge device without compaction and for smooth and controlled transfer of the device to air channels thereby avoiding compaction, and or spillage, so that on repeated operation, the desired metered dose will be dispensed each time a patient uses the apparatus.

[0078] It will be understood that the controlled smooth movement of the embodiments of the invention described herein does not affect individual doses dispensed when a patient uses the apparatus on inhalation. The apparatus seeks to prevent inadvertent multiple dosing as a result of multiple actuations before use by a patient. In this preferred embodiment, (Fig. 15), the controlled smooth movement changes the method by which the prior art slide carrier is transferred to the inhalation position. Instead of suddenly releasing the slide carrier as the yoke lower descends, the trigger component for the second zone has a sloped portion instead of the ledge in the second zone of the prior mechanism. The first zone remains the same as the previous design, a sudden drop generates the metering pulse from the bellows.

[0079] As the yoke lower reached the second zone the movement is controlled by the opening of the mouthpiece cover. The yoke lower ledge has also been replaced by a slope. This controls the position of the slide carrier. The slide carrier position during transfer is now linked to the mouthpiece cover. Instead of the sudden stop against the hopper upper part, the slide carrier is gradually allowed to transfer across to the inhalation position, and the stopping is more controlled, and very smooth.

[0080] As a result of the smooth transfer, there is no jolting of the powder, and only a very small amount, if any, is spilled. A single actuation results in the same pharmaceutical performance as the prior mechanism, the difference is apparent for multiple actuations.

What is claim is:

1. A dry powder inhalation apparatus, comprising a reservoir for medicament, a mouthpiece for insertion in the mouth of a user for inhalation of a predetermined dose of medicament, a delivery channel between a discharge outlet of the reservoir and the mouthpiece for delivering said predetermined dose of medicament, a device normally held adjacent the reservoir for receiving said predetermined dose of medicament from said discharge outlet and transferring it to the delivery channel, and a mechanism adapted to release the device and permit controlled movement thereof to the delivery channel for said delivery.
2. The apparatus of claim 1, further comprising a cup for receiving the said dose and a longitudinally slidable body mounting said cup, the mechanism comprising abutment means which is movable to release the device for movement to the delivery channel.
3. The apparatus of claim 2, further comprising the abutment means being bodily movable by an actuation means.
4. The apparatus of claim 3, comprising a yoke member which is shiftable bodily towards and away from the mouthpiece, and mounting limbs one of which has a cam follower for following a cam which is rotatable for actuation of the yoke member which carries the actuation means in the form of a ramp up which a part at least of the device can travel for controlled movement thereof towards the delivery channel.
5. The apparatus of claim 4, the actuation means comprising an element for returning the device to the discharge outlet.
6. The apparatus of claim 5, the element comprising an inclined ledge down which the part travels to said charging position.
7. The apparatus of claim 6, wherein the yoke member comprises a lower (in use) cam which is resilient and has a surface profile.
8. The apparatus of claim 7, wherein the surface profile is convex in configuration.

9. The apparatus of claim 8, wherein the lower in use end of the yoke is adjacent the mouthpiece.
10. The apparatus according to any preceding claim, wherein the abutment means comprises a resilient member which is flexible out of the path of the device.
11. The apparatus of claim 10, wherein the resilient member comprises a one piece member of substantially J- or U-configuration one limb of which is movable for releasing the device.
12. The apparatus of claim 11, wherein the movable limb has a finger-operable tab projecting from a housing of the apparatus.
13. The apparatus of claim 12, wherein the tab has indicia indicating the direction of flexing of the limb for release of the device.
14. The apparatus of claim 3, wherein the actuation means comprises a resiliently mountable slidable member which has a tab projecting through a bore of a body of the apparatus for releasing the device.
15. The apparatus of claim 14, wherein the slidable member having indicia which can be read through the bore for indicating the position of the device.
16. The apparatus of claim 15, wherein the indicia comprises a colour code indicia.
17. The apparatus of claim 3, wherein the actuation means comprises a resiliently and pivotably mounted detent means which is shiftable bodily about its pivot axis to release the device.
18. The apparatus of claim 17, wherein the detent means has a finger grippable projection which projects there from and through a slot in the body of the apparatus for bodily shifting of the detent when the projection is moved along the slot.
19. The apparatus of claim 3, wherein the actuating means comprises a resiliently mounted plunger means which has one end projecting through a bore in a body of the device and an opposite end adapted to engage the device for shifting same bodily to said delivery channel.
20. The apparatus of claim 19, wherein the plunger means has a substantially cylindrical body member connecting the one end and the opposite end, the opposite end being enlarged relative to the body member.

21. The apparatus of claim 20, wherein there is a relatively soft cushion member of the opposite end for contacting the device.
22. The apparatus of claim 3, wherein the actuation means comprises an electrical, electronic or electro-mechanical means.
23. The apparatus of claim 22, wherein the actuation means comprises a solenoid means actuated by a switch device for actuation of the device.
24. The apparatus of claim 23, wherein the switch device is operable manually by a user.
25. The apparatus of claim 23, wherein the switch device is operable by inhalation of a breath by a user.
26. The apparatus according to any of Claims 22 to 25, further comprising a power source for the electrical, electronic or electro-mechanical means.
27. The apparatus according to any preceding claim, further comprising a cover for an end of the discharge channel at the mouthpiece, the cover being movable between a position covering the discharge channel and a position for discharging said dose, whereby to allow actuation of the mechanism.
28. The apparatus of claim 27, wherein the cover comprises a relatively rigid disc carried by opposed arms which at an end thereof opposite the disc mount a cam which has a profile for allowing movement of a cam follower in a direction away from the device whereby to allow operation of the actuation means for bodily movement of the abutment means.
29. The apparatus of claim 28, wherein the disc in its first mentioned position is housed within a guard of the apparatus, which guard is pivotably mounted for access to the disc.
30. The apparatus of claim 3, further comprising a breath actuable apparatus.
31. The apparatus of claim 30, wherein the mechanism is between opposed spaced walls of the reservoir and has a member which is retractable on a user taking a breath on the mouthpiece.
32. The apparatus of claim 31, wherein the mechanism comprises cooperating rotatable means one of which has a detent for engaging the device and the other of which is

operable to maintain the detent in engagement with the device and to allow rotation of the one means to release the detent and device.

33. The apparatus of claim 32, wherein the mechanism further comprises a stop member retractable as a user takes a breath on the mouthpiece, and adapted to release the other rotatable means and the detent.
34. The apparatus of claim 33, wherein the rotatable means comprises cam or gear means.
35. The apparatus of claim 33 or 34, wherein the stop member comprises an elongate mounted member which is biased to engage the other rotatable means and a flap valve which is operable to allow air into a space between said opposed walls to equalise air pressure inside and outside the space and bias the elongate member to operate the cam or gear means.
36. The apparatus according to any preceding claim, wherein the device is mounted under pressure resilient means.
37. The apparatus of claim 36, wherein the pressure resilient means comprises spring means.
38. The apparatus according to any preceding claim, comprising a damper means for damping movement of the device.

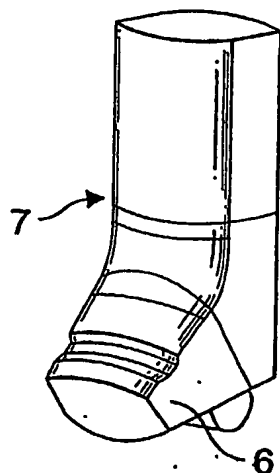


FIG. 1

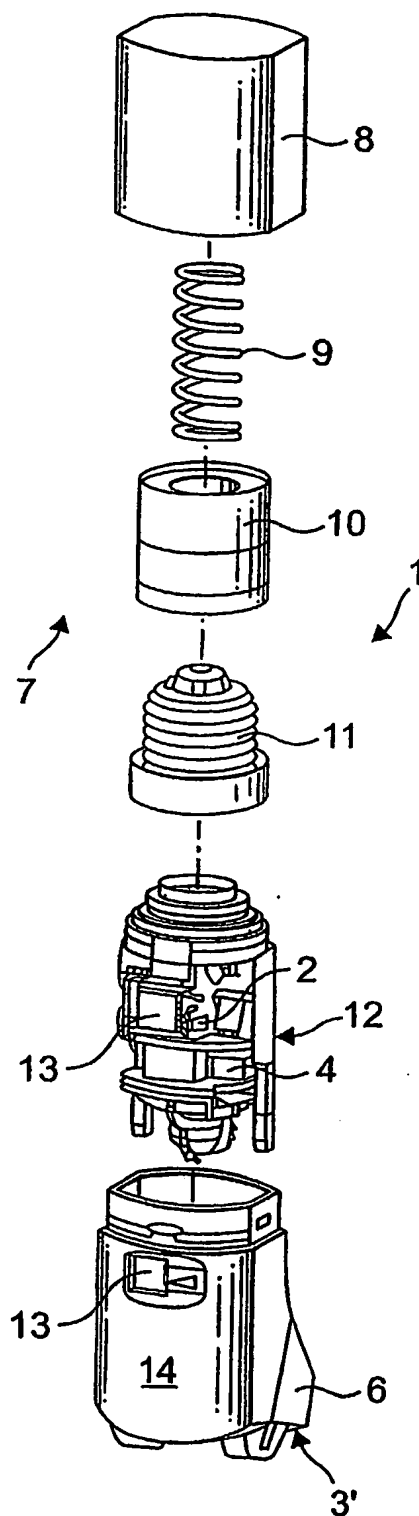


FIG. 2

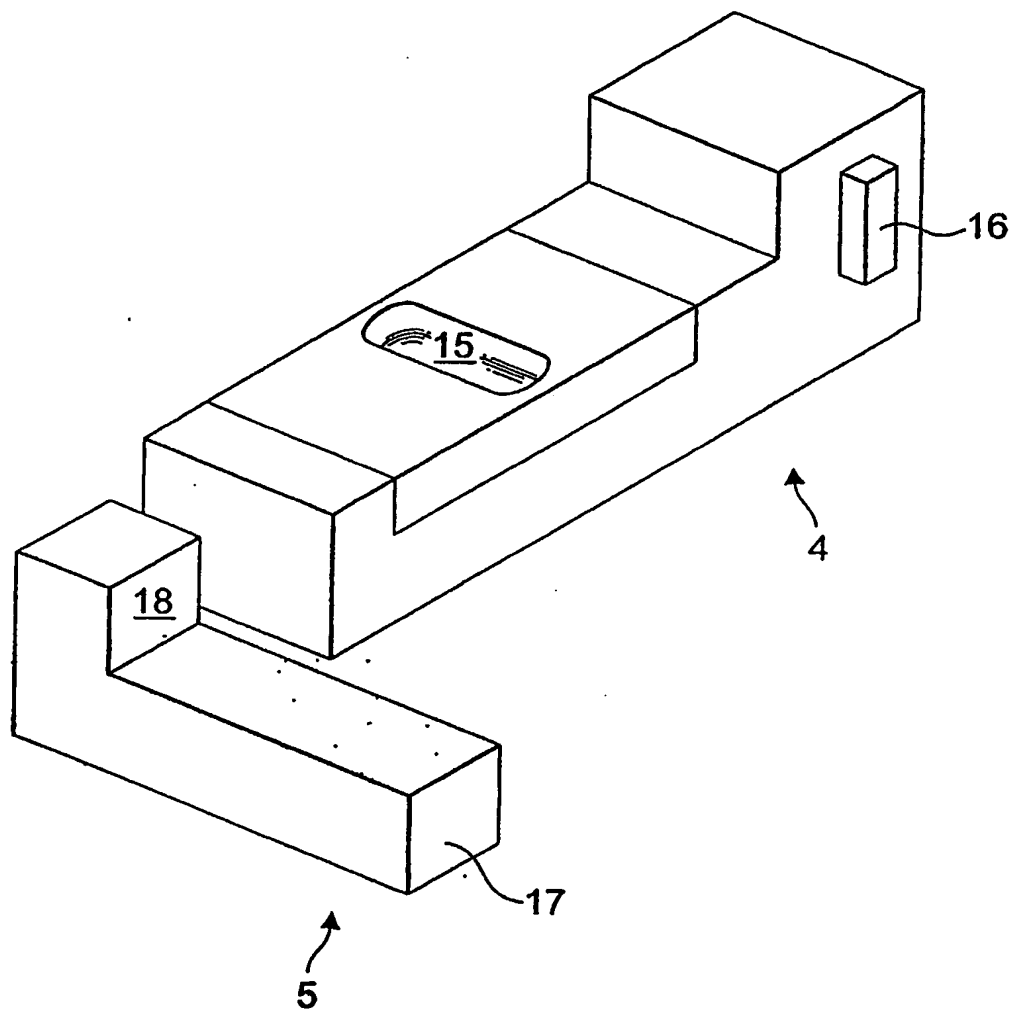


FIG. 3

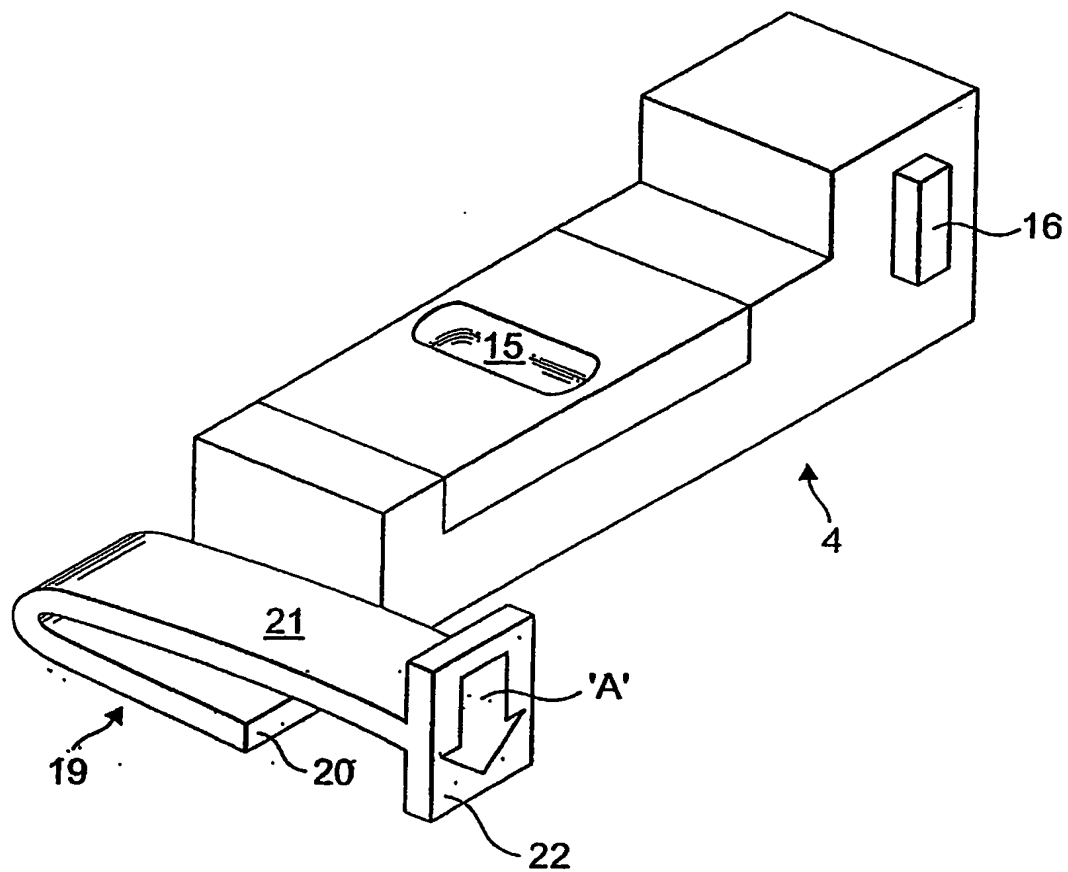


FIG. 4

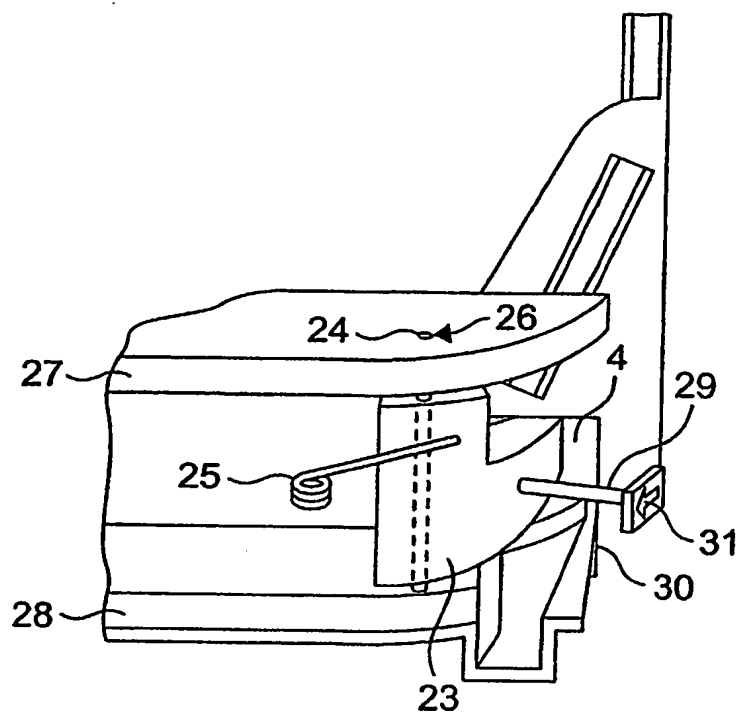


FIG. 5A

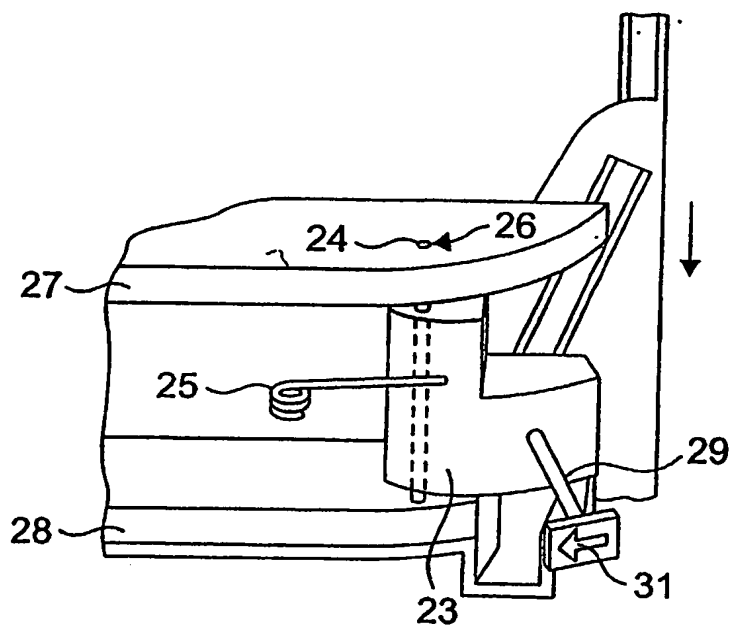


FIG. 5B

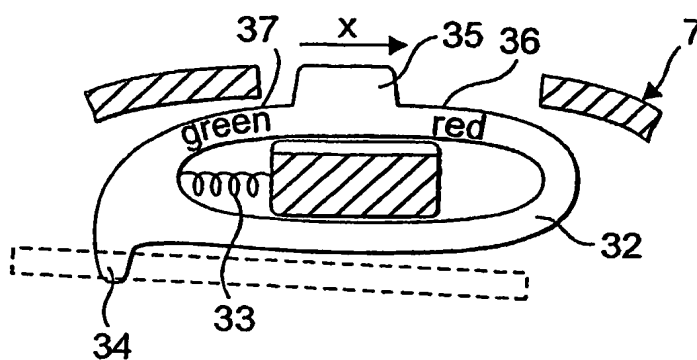


FIG. 6

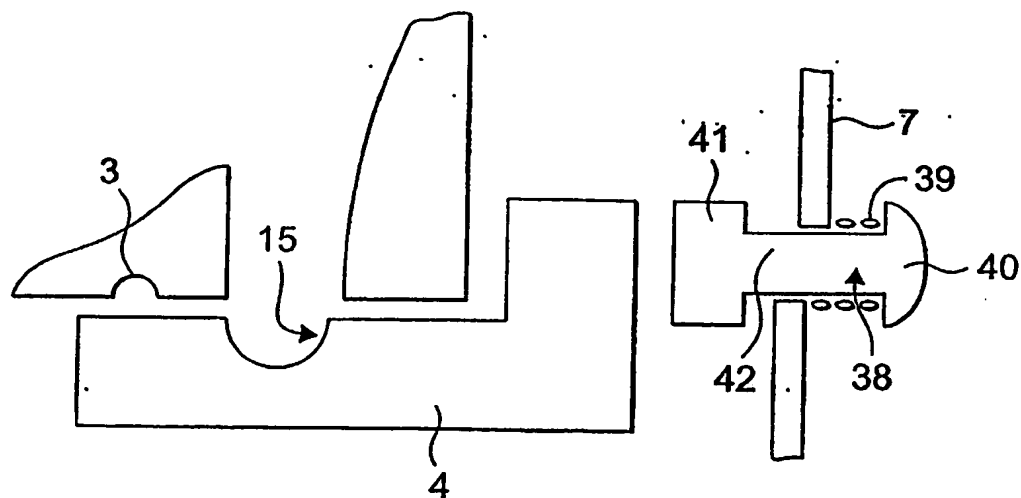


FIG. 7

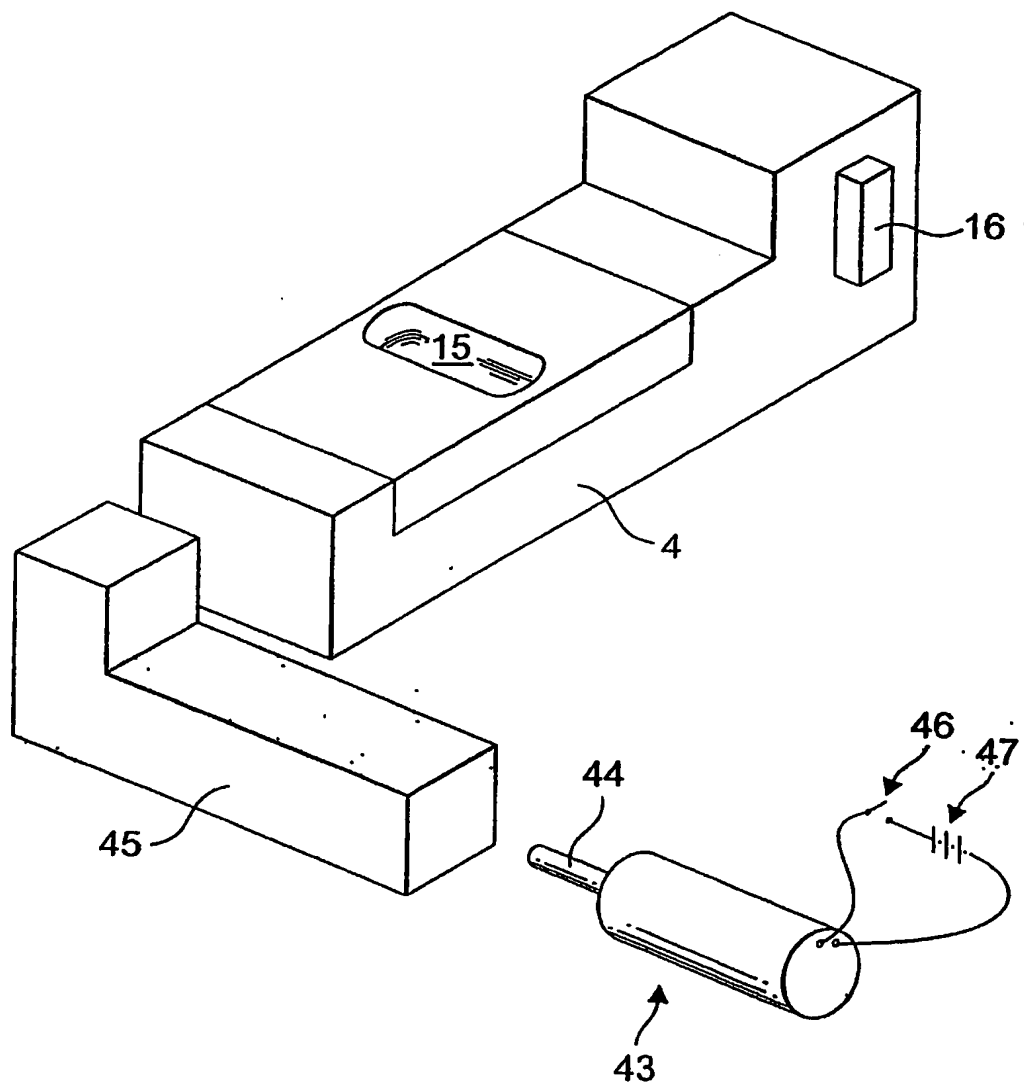


FIG. 8

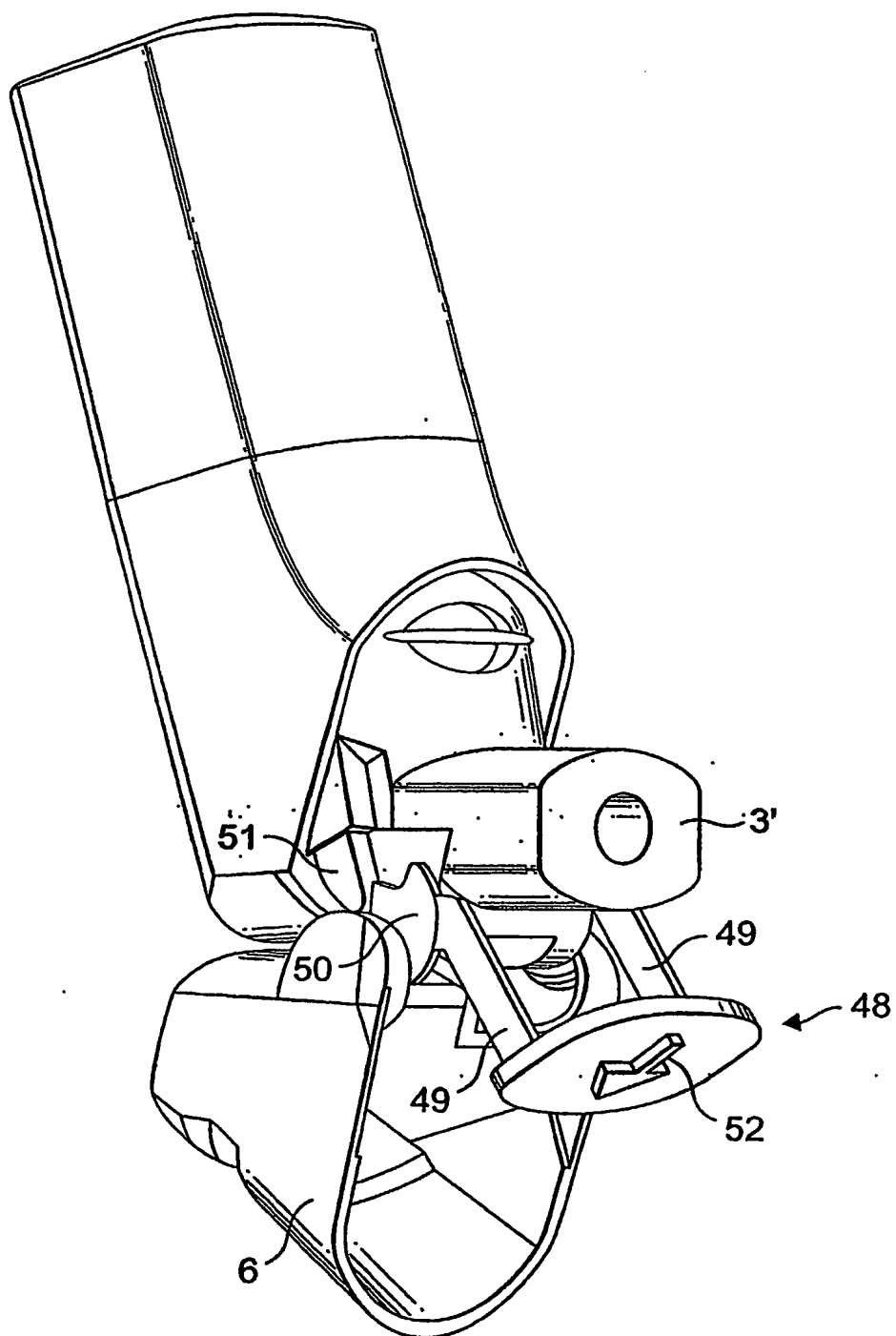


FIG. 9

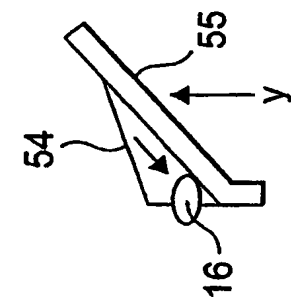


FIG. 10D

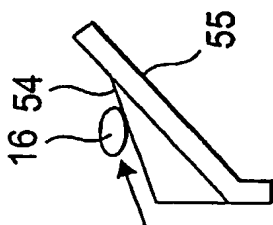


FIG. 10C

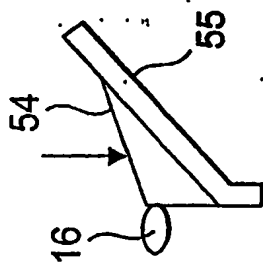


FIG. 10B

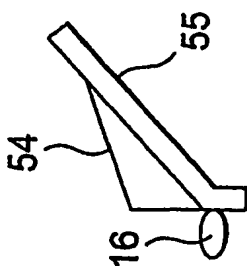


FIG. 10A

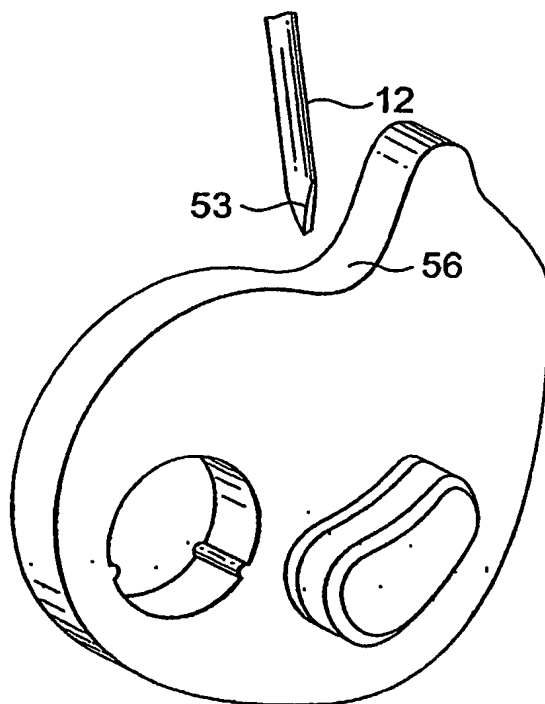


FIG. 11

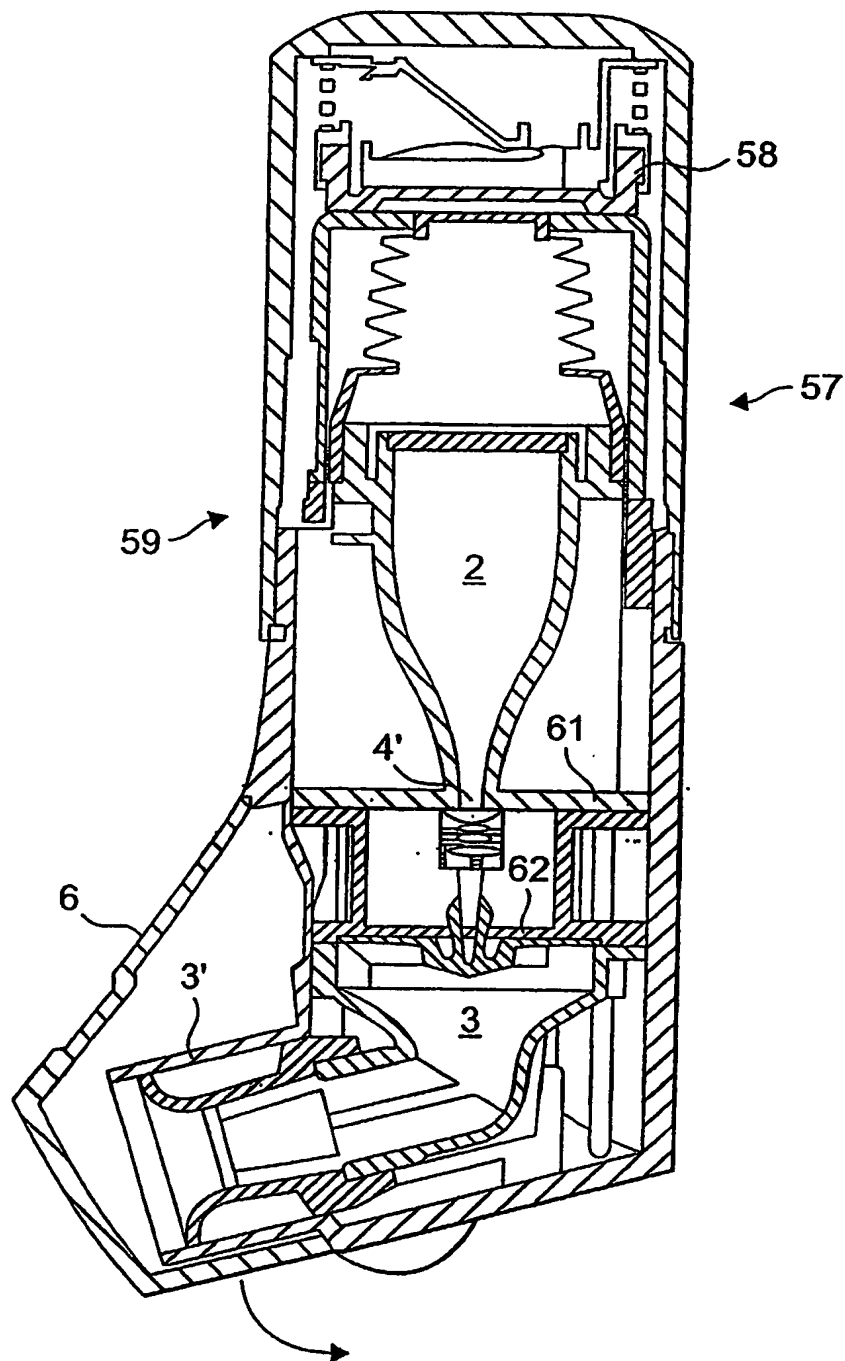


FIG. 12

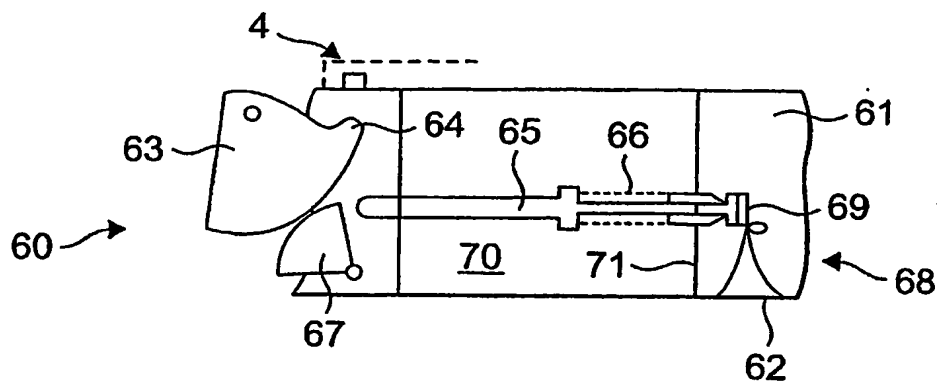


FIG. 13

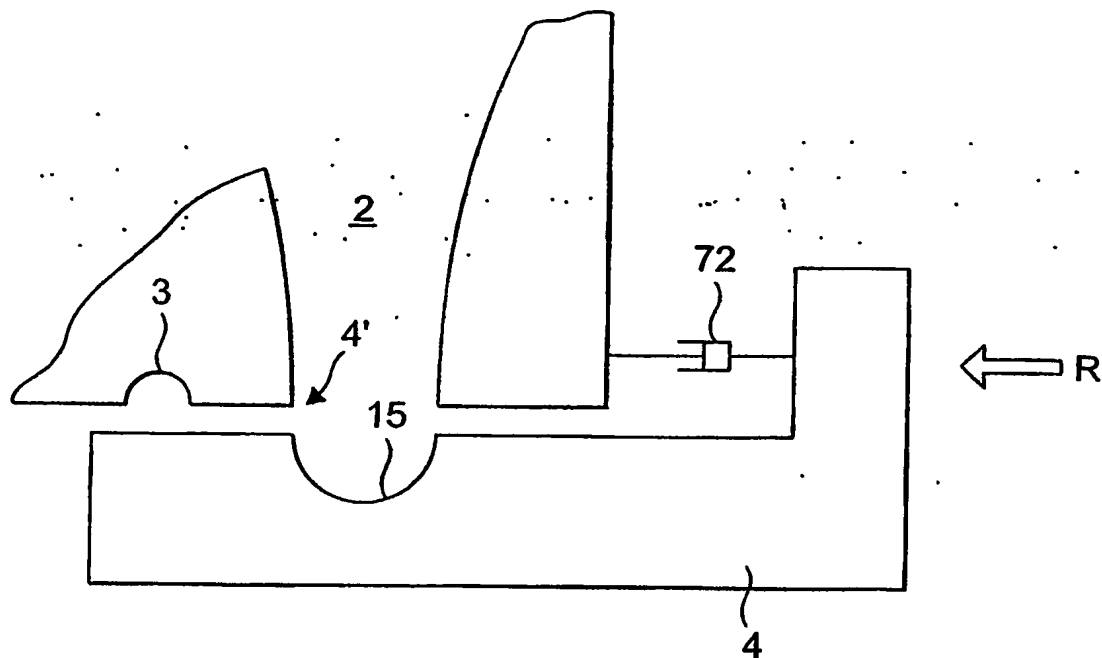


FIG. 14

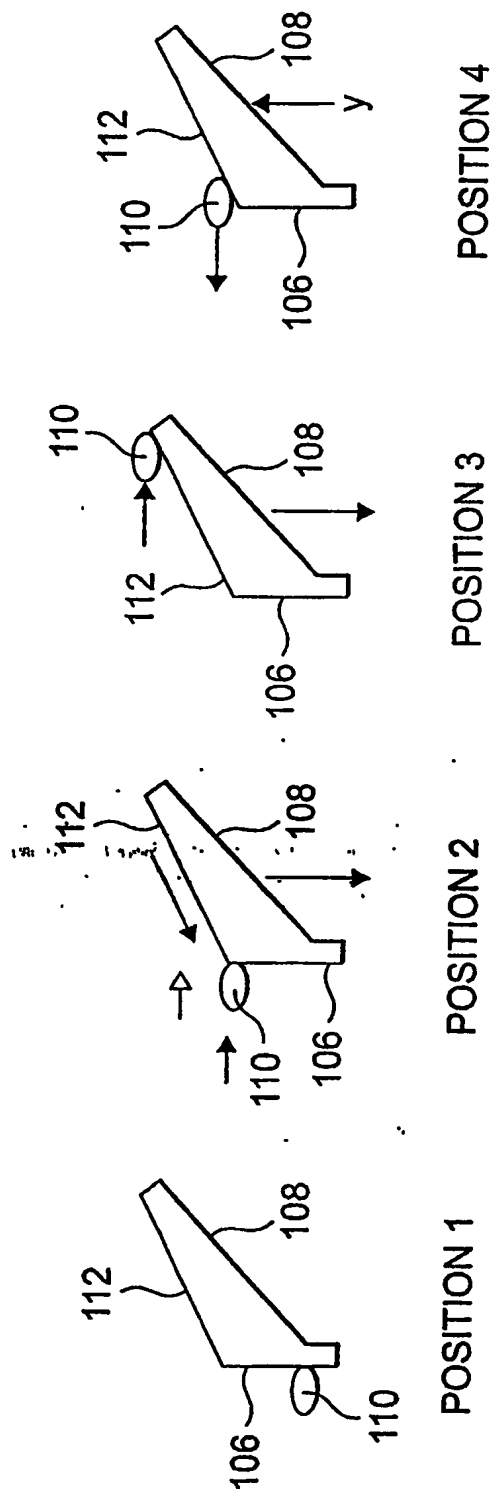



FIG. 15

IN THE MATTER of United States Patent Application Number 10/574,386

EXHIBIT SR2 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY



SAMANTHA CLAIRE RADLEY



PRACTISING SOLICITOR



Subsidiary of **IVAX Corporation**

Mr David O Leary
25 Newburgh Road
Little Thurrock
Grays
Essex RM17 6UG

Albert Basin, Royal Docks
London E16 2QJ
Telephone 08705 02 03 04
Fax 08705 32 33 34

5th January 2007

Dear David,

RE: US National Phase of PCT/2004/032160 for
DRY POWDER INHALATION APPARATUS
in the name of Norton Healthcare Limited

Please find enclosed a declaration for use in the prosecution of the above patent application in the United States by Norton Healthcare Limited. Please can you sign and date the declaration where indicated. The Declaration is required so that you are formally recognised by the USPTO as an inventor for this patent application.

There is also an Assignment form that should be witnessed by someone who knows you at the time of your signing. Please can you sign the assignment in the presence of such a witness who should then also sign the assignment to show that your signature is indeed your true signature. Again, this assignment is merely a formality that is required by the USPTO to confirm that as an employee of Norton Healthcare Ltd, you assigned your rights in the invention to Norton Healthcare Ltd. In English law, an employee automatically assigns their rights in an invention to their employer.

This declaration and assignment only relate to this patent application. Consequently, if you are named as an inventor on other applications, we will have to contact you again to request your signature. Thank you for your cooperation.

Please endeavour to return the signed forms in the stamped, addressed envelope provided by 17th January 2007. Unfortunately, the USPTO set a time limit to file these documents and if we do not meet the date, fines are incurred.

If you have any queries, please do not hesitate to contact the Patent Department.

Yours sincerely

David W. Cottam Ph.D.
Intellectual Property Counsel
Norton Healthcare Limited

IN THE MATTER of United States Patent Application Number 10/574,386

EXHIBIT SR3 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY


SAMANTHA CLAIRE RADLEY


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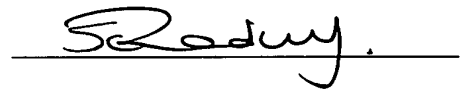
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IN THE MATTER of United States Patent Application Number 10/574,386

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SAMANTHA CLAIRE RADLEY


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IN THE MATTER of United States Patent Application Number 10/574,386

EXHIBIT SR5 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY



SAMANTHA CLAIRE RADLEY



PRACTISING SOLICITOR



Jaz Ghick/LON/TEVA/IL
27/03/2007 14:40

To Samantha Radley/LON/TEVA/IL@TEVANEW
cc
bcc
Subject Re: Fw: Inventors Details

Hi Sam

There has been no reference requested for those on your list below.

Kind Regards

Jaz Ghick
HR Advisor

Tel: 020 7540 7195
Fax: 020 7540 7209
email: jaz.ghick@tevaeu.com
www.tevapharma.com

Teva, HR Department,
Building V,
The London Road Campus,
London Road,
Harlow, Essex
CM17 9LP
Samantha Radley/LON/TEVA/IL



Samantha
Radley/LON/TEVA/IL
26/03/2007 09:57

To jaz.ghick@tevauk.com
cc annette.cunningham@tevaeu.com,
david.cottam@teveeu.com
Subject Fw: Inventors Details

Hi Jaz,

Hope you had a good weekend.

Please call me re the below. This is getting very pressing now, I have a very close deadline in the states and I am on holiday next week.

Thanks,

Mrs Samantha Radley
Patent Administrator
Teva Europe Patent Department
Building V
London Road Campus
London Road
Harlow
Essex CM17 9LP

Tel: 020 7540 7242
Fax: 020 7540 7029
email: samantha.radley@tevaeu.com

----- Forwarded by Samantha Radley/LON/TEVA/IL on 26/03/2007 09:54 -----
Samantha Radley/LON/TEVA/IL

06/03/2007 15:15

To jaz.ghick@tevauk.com
cc
Subject Inventors Details

Hi Jaz,

Further to our earlier conversation, please can you have a look to see if there's been any enquiries from subsequent employers with regard to the following inventors once they left Ivax/Norton, and let me have details if there have been:-

Yogesh Dandiker
Donald MacDonald
Ramesh Yanamandra
Anayo Michael Ukeje
Michael Goller
David O'Leary /
Kee Tee Sean

Did you say that you had a temp coming in on Thursday who you could give this to? That would be a good timescale. I'm up against several deadlines in the States.

If you have any questions, please give me a call.

Thanks,

Sam

Mrs Samantha Radley
Patent Administrator
Teva Europe Patent Department
Albert Basin
Royal Docks
LONDON E16 2QJ

Tel: 020 7540 7242
Fax: 020 7540 7029
email: samantha.radley@tevaeu.com

Filed on behalf of Norton Healthcare Limited
Deponent: S. C. Radley
First Affidavit of the Deponent
Date of Swearing: 24 April 2007
Exhibits: SR1-4

IN THE MATTER of United States Patent Application Number 10/574,386

AFFIDAVIT OF SAMANTHA CLAIRE RADLEY

I, SAMANTHA CLAIRE RADLEY, of 79a Gellatly Road, London SE14 5TU
Patent Administrator, MAKE OATH and say as follows:

1. I am a Patent Administrator for Norton Healthcare Limited ("Norton") and I make this affidavit in support of Norton's United States patent application number 10/574,386 entitled "Dry Powder Inhalation Apparatus". In so far as the content of this affidavit is within my personal knowledge it is true, and so far as it is not within my personal knowledge it is true to the best of my knowledge information and belief.
2. On 3 August 2006, I sent a bundle of documents consisting of a Declaration for Utility or Design Patent Application, a copy of US Patent Application No. 10/574,386 and an Assignment of Utility Application form by DHL courier to 28A Loampit Hill, Lewisham, London SE13 7SW, the last known address of Rachel Striebig. The package was returned by DHL marked "Return to sender. Not known at this address". I present the DHL courier bag and its contents as exhibit SR1.
3. On or around the 23rd August 2006, I interrogated an internet based website called "BT.com". The website is a database that contains current United Kingdom electoral roll details and residential telephone numbers for residents in the United Kingdom. My enquiry revealed a new address for Rachel Striebig: Flat 4, Cyna Court, Cambridge Road, London E11 2PW. I present the result of the search of the BT.com website as exhibit SR2.
4. On 23 August 2006, I sent the bundle of documents described in paragraph 2 above to Flat 4, Cyna Court, Cambridge Road, London E11 2PW. No documentation has been returned to me at Norton Healthcare Limited to date.
5. On 2nd November 2006, I sent the bundle of documents described in paragraph 2 above to Flat 4, Cyna Court, Cambridge Road, London E11 2PW. The package was returned to me. There is writing on it but I can not determine what it says. I present the covering letter dated 2nd November and the returned DHL package cover as exhibit SR3.

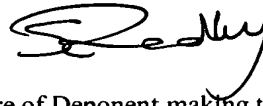
6. On 5th January 2007, I sent the bundle of documents described in paragraph 2 to Rachel Striebig at Flat 4, Cyna Court, Cambridge Road, London E11 2PW. The courier was unable to deliver to Ms Striebig. The package is being held by DHL awaiting collection by Ms Striebig. As of 12th April 2007, collection had not taken place. I present a copy of the DHL tracking report as exhibit SR4.

7. On 12 April 2007, I rang the telephone number detailed on exhibit 2. There was no reply and no voicemail was available to leave a message.

8. I believe that Ms Striebig either does not live at Flat 4, Cyna Court, Cambridge Road, London E11 2PW, or she is refusing to sign and return documents.

Sworn at Broomfield House
62-65 Chandos Place
London WC2N 4LP

this 24 day of
April 2007



Signature of Deponent making the Affidavit

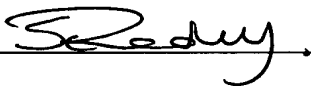
Before me,

Ayesha Brannell
Practising Solicitor at
Shepherd and Wedderburn LLP
Condor House
10 St. Paul's Churchyard
LONDON
EC4M 8AL



Signature of Authorised Witness

EXHIBIT SR1 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY



SAMANTHA CLAIRE RADLEY



PRACTISING SOLICITOR



Subsidiary of **IVAX** Corporation

Ms Rachel Strong
23A Loampit Hill
Lewisham
London SE13 7SW

Albert Basin, Royal Docks
London E16 2QJ

Telephone 08705 02 03 04
Fax 08705 32 33 34

3rd August 2006

Dear Rachel,

RE: US National Phase of PCT/2004/032160 for
DRY POWDER INHALATION APPARATUS
in the name of Norton Healthcare Limited

Sent 2 Nov 2006
Recd 5/1/07

Please find enclosed a declaration for use in the prosecution of the above United States patent application by Norton Healthcare Limited. Please can you sign and date the declaration where indicated.

There is also an Assignment form that should be witnessed by someone who knows you at the time of your signing. Please can you sign the assignment in the presence of such a witness who should then also sign the assignment to show that your signature is indeed your true signature.

Please return the forms in the stamped, addressed envelope provided as quickly as possible.

Thanks for your help.

Best regards.

Yours sincerely

David W. Cottam Ph.D.
Intellectual Property Counsel
Norton Healthcare Limited

DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet
Page <u>1</u> of <u>1</u>	

Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle (if any))				Family Name or Surname			
Rachel				Striebig			
Inventor's Signature				Date			
Residence: City		State		Country		Citizenship	
London				United Kingdom		United Kingdom	
Mailing Address:		28A Loampit Hill, Lewisham					
City		State		Zip		Country	
London				SE13 7SW		United Kingdom	

Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle (if any))				Family Name or Surname			
Inventor's Signature				Date			
Residence: City		State		Country		Citizenship	
Mailing Address:							
City		State		Zip		Country	

Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle (if any))				Family Name or Surname			
Inventor's Signature				Date			
Residence: City		State		Country		Citizenship	
Mailing Address:							
City		State		Zip		Country	

Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle (if any))				Family Name or Surname			
Inventor's Signature				Date			
Residence: City		State		Country		Citizenship	
Mailing Address:							
City		State		Zip		Country	

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
21 April 2005 (21.04.2005)

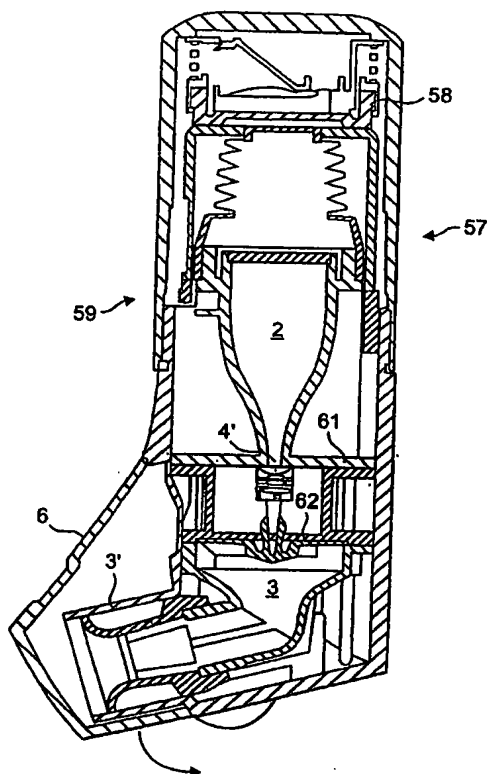
PCT

(10) International Publication Number
WO 2005/034833 A2

- (51) International Patent Classification⁷: **A61J**
- (21) International Application Number: **PCT/US2004/032160**
- (22) International Filing Date: **2 October 2004 (02.10.2004)**
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data:
0323085.1 **2 October 2003 (02.10.2003)** **GB**
- (71) Applicant (for BB only): **IVAX CORPORATION**
[US/US]; 4400 Biscayne Boulevard, Miami, FL 33137 (US).
- (71) Applicant (for all designated States except US): **NORTON HEALTHCARE LTD.** [GB/GB]; Albert Basin, Royal Docks, London EC16 2QJ (GB).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **BARNEY, Brian** [GB/GB]; 50 Stortford Road, Great Dunmow, Essex CM6 1DN (GB). **O'LEARY, David** [GB/GB]; 25 Newburgh Road, Little Thurrock Grays, Essex, RM17 6UG (GB). **STRIEBIG, Rachel** [GB/GB]; 28A Loampit Hill, Lewisham, London SE13 7SW (GB).
- (74) Agent: **STEINBERG, Michael, A.**; 4400 Biscayne Boulevard, Miami, FL 33137 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,

[Continued on next page]

(54) Title: **DRY POWDER INHALATION APPARATUS**



(57) Abstract: The invention relates to dry powder inhalation apparatus usually operable by breath of a user which provides for controlled and smooth transfer of medicament during multiple actuations by a user. A mechanism of the apparatus for achieving this controlled and smooth transfer includes a device (4) normally held adjacent a reservoir for receiving medicament in a cup or receptacle (15) and which is generally movable transversely of a longitudinal axis of the apparatus to delivery channels of the apparatus. This bodily shifting of the device (4) is achieved by a yoke acting on an abutment (16) thereof. Spillage of medicament in the apparatus is avoided.



TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(84) **Designated States** (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI,

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DRY POWDER INHALATION APPARATUS

Inventors: Brian Barney, David O'Leary and Rachel Striebig
(Attorney Docket: NHC0083-UNK)

BACKGROUND OF THE INVENTION

[0001] The invention relates to dry powder inhalation apparatus. This apparatus administers a dry powder medicament in a desired pre-determined dose to a user of the apparatus who actuates the apparatus manually and then breathe in the predetermined dose, or, on taking a breath, would automatically actuate the device for breathing in the predetermined dose of medicament. Breath actuation is typically used to dispense the desired dose of medicament into the lungs of the patient. The medicament is carried in air during inhalation so that fine particles are carried into the lungs and heavier particles are retained in the buccal cavity.

[0002] Typically such an apparatus includes a reservoir for containing the medicament in dry powdered form. The reservoir contains medicament for a particular number of doses. The doses are metered from the reservoir one dose at a time on actuation by a user. The apparatus also includes an air inlet or inlets for taking up or entraining the medicament for passage along airways through a mouthpiece of the apparatus and into the lungs of the user when the user takes a breath.

[0003] The amounts of medicament in a particular dose are small and received from the reservoir in a device having a receptacle or cup for receiving a metered dose of medicament. The device then shifted bodily in order to transfer the metered dose to the air channels. The body of the device seals off a discharge outlet from the reservoir during this transfer motion.

[0004] In known apparatus, a mechanism transfers a slide carrier assembly carrying a metered dose by releasing the slide carrier off the end of a lower ledge of a yoke. A yoke lower moves as a trigger is rotated by a mouthpiece cover opening. The trigger has two drop zones. The first of these is used to generate sudden movement of the yoke lower to compress a bellows for metering. The second drop zone is also sudden, and it is during this zone that the yoke lower releases the slide carrier. The transfer spring forces the slide carrier across a

channel between a hopper upper and a hopper lower components. When the slide carrier hits the side wall of the hopper upper the slide carrier stops abruptly.

[0005] However, even though a relatively small amount of powder is being dispensed, the powder making up each dose can be compacted which can cause more than the prescribed dosage to be received in the cup.

[0006] Moreover, even if there is no compaction, the medicament can be spilled from the cup on transfer. Consequently, although there is a collection well for receiving spilled medicament, the required desired dosage may not be administered when the user takes a breath.

[0007] Both disadvantages of compaction and spillage result from the way in which the device is transferred from the discharge outlet of the reservoir to the position for passage of the medicament into the air channels.

[0008] Accordingly, the present invention mitigates these disadvantages.

SUMMARY OF THE INVENTION

[0009] According to the present invention, there is provided dry powder inhalation apparatus, comprising a reservoir for medicament, a mouthpiece for insertion in the mouth of a user for inhalation of a predetermined dose of medicament, a delivery channel between a discharge outlet of the reservoir and the mouthpiece for delivering said predetermined dose of medicament, a device normally held adjacent the reservoir for receiving said predetermined dose of medicament from said discharge outlet and transferring it to the delivery channel, and a mechanism adapted to release the device and permit controlled movement thereof to the delivery channel for said delivery.

[0010] It will be understood that in using the invention it is possible to provide for controlled, smooth transfer of a required dose of medicament in a two-stage operation. Movement of the device is interrupted after charging with medicament for subsequent controlled movement to the position for passage of the medicament into air channel(s) forming the discharge channels.

- [0011] The device may comprise a cup for receiving said dose and a longitudinally slidable body mounting said cup, the mechanism comprising abutment means which is movable to release the device for movement to the delivery channel.
- [0012] The abutment means may preferably be bodily movable by an actuation means. This provides for positive operation and actuation.
- [0013] The abutment means may also comprise a resilient member which is flexible out of the path of the device. This again provides a positive operation and actuation, particularly when the resilient member may comprise a one piece member of substantially J- or U-configuration, one limb of which is movable for releasing the device.
- [0014] The movable limb may have a finger-operable tab projecting from a housing apparatus, and the tab may have indicia indicating the direction of flexing of the limb for release of the device.
- [0015] The actuation means may comprise a resiliently mountable slidable member which has a tab projecting through a bore of a body of the apparatus for releasing the device. This also provides for positive operation and actuation, the slidable member preferably having indicia which can be read through the bore for indicating the position of the device. The indicia may suitably comprise a colour code indicia.
- [0016] The actuation means may further comprise a resiliently and pivotably mounted detent means which is shiftable bodily about its pivot axis to release the device.
- [0017] Suitably, the detent means may have a finger grippable projection which projects therefrom and through a slot in the body of the apparatus for bodily shifting of the detent when the projection is moved along the slot.
- [0018] The actuating means may further comprise a resiliently mounted plunger means which has one end projecting through a bore in a body of the device and an opposite end adapted to engage the device for shifting same bodily to said delivery channel.
- [0019] The plunger means may suitably have a substantially cylindrical body member connecting the one end and the opposite end, and the opposite end may be enlarged relative to the body member.
- [0020] There may be a relatively soft cushion member of the opposite end for contacting the device. This provides for a cushioned, controlled motion of the device.

- [0021] The actuation means may comprise an electrical, electronic or electro-mechanical means.
- [0022] The actuation means may comprise a solenoid means actuated by a switch device for actuation of the device. Suitably, the switch device may be operable manually by a user, or alternatively the switch device may be operable by inhalation of a breath by a user. In either mode, a positive operation of the device can be achieved.
- [0023] There may be a power source for the electrical, electronic or electro-mechanical means.
- [0024] There may be a cover for an end of the discharge channel at the mouthpiece, and the cover may be movable between a position covering the discharge channel and a position for discharging said dose, whereby to allow actuation of the mechanism.
- [0025] The cover may suitably comprise a relatively rigid disc carried by opposed arms which at an end thereof opposite the disc mount a cam which has a profile for allowing movement of a cam follower in a direction away from the device whereby to allow operation of the actuation means for bodily movement of the abutment means.
- [0026] The disc in its first mentioned position may be housed within a guard of the apparatus, which guard is pivotably mounted for access to the disc.
- [0027] There may be a yoke member which is shiftable bodily towards and away from the mouthpiece and mounting limbs, one of which has a cam follower for following a cam which is rotatable for actuation of the yoke member which carries the actuation means in the form of a ramp up which a part at least of the device can travel for controlled movement thereof towards the delivery channel. This again provides a positive operation, particularly when the actuation means comprises a return element for returning the device to the charging position.
- [0028] Such a return element may suitably comprise an inclined ledge down which the part travels to said discharge outlet.
- [0029] The apparatus may be a breath actuable apparatus.
- [0030] The mechanism may be between opposed spaced walls of the reservoir and may have a member which may be retractable on a user taking a breath on the mouthpiece.
- [0031] The mechanism may comprise cooperating rotatable means one of which has a detent for engaging the device and the other of which is operable to maintain the detent in

engagement with the device and to allow rotation of the one means to release the detent and device.

[0032] The mechanism may further comprise a stop member, retractable as a user taking a breath on the mouthpiece, and adapted to release the other rotatable means and the detent.

[0033] The rotatable means may comprise cam or gear means.

[0034] The stop member may suitably comprise an elongate mounted member which is biased to engage the other rotatable means and a flap valve which is operable to allow air into a space between said opposed walls to equalise air pressure inside and outside the space and bias the elongate members to operate the cam or gear means.

[0035] The device may be mounted under pressure resilient means, suitably spring means.

[0036] There may also be damper means for damping movement of the device.

[0037] Embodiments of the apparatus according to the invention are hereinafter described, by way of example, with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0038] Fig. 1 shows a perspective view of a typical dry powder inhalation apparatus;

[0039] Fig. 2 shows an exploded perspective view of a typical dry powder inhalation apparatus like that of Fig. 1;

[0040] Fig. 3 shows to a much enlarged scale a perspective view of an embodiment of device for dispensing a desired dose of medicament according to the invention;

[0041] Fig. 4 shows to a much enlarged scale a perspective view of a second embodiment of device for dispensing a desired dose of medicament according to the invention;

[0042] Figs. 5A and 5B shows respectively two operative positions of a third embodiment of apparatus according to the invention;

[0043] Fig. 6 shows a plan view of a fourth embodiment of apparatus according to the invention;

[0044] Fig. 7 shows schematically a fifth embodiment of apparatus according to the invention;

[0045] Fig. 8 shows schematically a perspective view of a further embodiment of apparatus according to the invention;

[0046] Fig. 9 shows schematically a further embodiment of inhalation device according to the invention;

[0047] Fig. 10 shows in (a) – (d) different positions of yet further apparatus embodying the invention;

[0048] Fig. 11 shows part of actuating mechanism of the embodiment of Fig. 10;

[0049] Fig. 12 shows schematically a breath operated dry powder inhalation device;

[0050] Fig. 13 shows part of the device of Fig. 12 shown in an embodiment according to the invention;

[0051] Fig. 14 shows a way of mounting the device of the apparatus of the previously described embodiment; and

[0052] Fig. 15 shows schematically a production model apparatus similar to that shown in Fig. 10, however in this embodiment a cam of the apparatus is solid.

DETAILED DESCRIPTION OF THE INVENTION

[0053] Referring to the drawings (see for example Figs. 1, 2, 3, 9), and in which like parts are referred to by like numerals where feasible, there is shown dry powder inhalation apparatus 1, comprising a reservoir 2 for medicament, a mouthpiece 3' for insertion in the mouth of a user for inhalation of a predetermined dose of a medicament, a delivery channel 3 between a discharge outlet 4' of the reservoir 2 and the mouthpiece for delivering said predetermined dose of medicament, a device 4 normally held adjacent the reservoir for receiving a predetermined dose of medicament from said discharge outlet and transferring it to the delivery channel, and a mechanism 5 adapted to release the device 4 and permit controlled movement thereof to the delivery channel for said delivery.

[0054] Fig. 1 shows the general outline of the inhalation apparatus 1 from in front there being a pivotable cover 6 at the bottom (and as used) of a body 7 of the device.

[0055] As shown in Fig. 2, the housing or body 7 of the apparatus 1 includes a cap 8, an internal spring 9, a yoke 10, a bellows 11, an actuating mechanism including a further yoke 12, a counter 13, viewable in the base 14 of the body 7 mounting the mouthpiece cover 6.

[0056] The mechanism 5 (Fig. 3. and Fig. 12 for example) includes the device 4 which is generally movable transversely of a longitudinal axis of the apparatus 1 for receiving in a cup or receptacle 15 a metered dose of powdered medicament which is then transferred by the shifting of the device 4 to the discharge channels or airways 3 which when a patient breathes in on sucking on the mouthpiece 3', removes the powdered metered dose from the cup or receptacle 15 so that it is entrained in the air and passes through the mouthpiece 3' into the lungs and mouth of the user. Charging of the cup or receptacle 15 with medicament is effected from a discharge outlet 4' (Fig. 12) of the reservoir 2 by the bellows 11 on movement of the yoke 10 in a position towards the mouthpiece 3', there being a part in the form of a shoulder, boss or abutment 16 of the device 4, for shifting the device longitudinally bodily from the discharge outlet 4' to the air delivery channel 3.

[0057] In order to provide a smooth operation, there is positioned at the fore end of the device 4 an abutment 5 which has physically to be moved bodily out of the way of the device and, as shown in Fig. 3, this abutment is of L-shape which on movement by finger pressure on an end 17 shifts the abutment 5 so that an upstanding integral part 18 thereof is clear of the adjacent end of the device 4 so that the device 4 can then be moved smoothly to the discharge position under pressure of a spring (which is not shown).

[0058] Fig. 4 shows a further embodiment in which the abutment comprises a resilient member 19 in the form of in the embodiment shown a J-shaped plastic spring-like member, the lower or shorter limb 20 of which is secured in the body 7 of the apparatus 1 and the upper limb 21 of which is able to be flexed out of the path of the device 4 on movement of a tab 22 downwardly as shown by the indicia 'A' in the form of an arrow on the outside surface thereof.

[0059] When the underside of the longer limb 21 meets the upper surface of the lower limb 20 and therefore cannot be lowered further, the user knows that there is a positive "stop", and the desired medicament is available for inhalation.

[0060] Turning now to Figs. 5A and 5B, the mechanism 5 includes a pivotable stop 23. The stop 23 is of generally L-shape and is mounted for pivotable movement on an axis 24 under spring pressure 25 which tends to bias it towards a position obstructing movement of the device 4.

[0061] The pivot 24 is mounted in holes 26 in facing members of upper and lower flanges 27, 28 of the reservoir or hopper 2.

[0062] There is a projection 29 from one limb of the abutment member 23, the projection 29 being accessible manually through an orifice 30 in a wall of the body 7 by a user who on turning the projection 29 in the direction shown by the arrow 31, releases the device 4 for smooth but positive motion to the discharge position, the projection 29 when it meets a blind wall of the orifice 30 effectively informing the user that the desired dosage of medicament is again available for inhalation.

[0063] Fig. 6 shows a yet further embodiment in which there is a slidable ring-shaped member 32 which is mounted under pressure of a spring 33 to be biased to a position in which a projection 34 of the ring 32 interferes with the motion of the device 4. The ring member 32 also includes a button 35 which projects through an opening or orifice 36 in a wall 7 of a body of the apparatus 1.

[0064] The ring 32 includes indicia 37 either in lettering or in colour, for example in red and green showing when the device 4 is not ready for dispensation (red) or is ready for dispensation and thus inhalation (green).

[0065] The user can read this indicia when the button 35 is pushed under finger or thumb pressure from left to right as shown by the arrow 'X' in Fig. 6, thereby releasing the device 4 and thus making the medicament ready for inhalation.

[0066] Turning now to Fig. 7, an embodiment is shown in which a button or plunger 38 mounted in a wall 7 of the apparatus 1 under spring 39 pressure is biased away from contact with an abutment of the device 4, but on actuation of a head 40 of the plunger inwardly the opposite end 41 thereof which is enlarged relative to a cylindrical body 42 of the plunger contacts the device 4 and shifts it bodily and smoothly to the left as viewed ready for discharge to the air channels, on inhalation.

[0067] Release of the button 38 retracts the plunger so that the device 4 itself can return for further charging, the device as in all embodiments, being mounted under spring pressure which biases it towards the charging position. The enlarged opposite end 41 of the plunger 38 may include a cushion (not shown) for providing a cushioned contact of the plunger with the device 4.

[0068] Fig. 8 shows a yet further embodiment in which there is an actuator 43 such as an electrical, electronic or electro-mechanical actuator having an extensible actuating member such as a piston rod 44 which on operation of the actuator 43 extends to push the abutment 45 of the

mechanism out of the path of the device 4, for discharge as before. The actuator 43 in this embodiment includes a switch 46, and a power source 47 such as a battery. The switch 46 may be operated manually, or automatically when a user takes a breath.

[0069] Turning now to Fig. 9, there is shown an embodiment in which the mouthpiece 3' is normally covered by a flap or disc 48 which is mounted on two arms 49 at the end of which opposite the flap or disc 48 there is a cam device 50 which operates the operating mechanism by allowing a cam follower 51 to follow the shape of the cam 50 thereby to allow the cup of the device to be charged and then for a mechanism like that labelled (5) in Fig. 3 but not shown in Fig. 9, to allow for smooth transfer of the device 4 for discharge of the inhalation dose with the medicament as described hereinbefore.

[0070] The flap, or cover 48, carries externally an indicia 52 such as an arrow to indicate to a user the direction in which the flap should be pivoted to effect operation and to expose the mouthpiece 3' for inhalation, the cover in the closed position of the mouthpiece being itself closed by a pivotable external cover 6.

[0071] Turning now to Figs. 10 and 11, there is shown schematically a mechanism in which the part 16 of the device 4 is initially in the rest position shown in (a) against a ratchet part of a yoke 12 which has a lower cam 53 and which is resilient and profiled in a direction orthogonal to that as viewed, as by being convex. When that yoke 12 is actuated and pulled down for charging the cup 15 with the desired dosage of medicament, the part 16 rides up the ratchet as shown at (b) and then, to effect transfer, it moves gently and smoothly upwardly along a ramp 54 owing to the resilience and profile of the ratchet, as shown at (c). On return of the ratchet upwardly, arrow 'Y', the part 16 of the device 4 is engaged by a downward sloping element 55 (left to right as viewed in (b)), and, in order to accommodate upward movement of the ratchet, the part 16 of the device 4 moves down the slope or return element 55 thereby returning the device 4 to the position for charging.

[0072] Fig. 15 shows schematically a production model of apparatus embodying the invention. In Fig. 15, there is shown a schematically mechanism in which the part 16 of Fig. 10 of the device 4 shown as 110 in Fig. 15, is initially in a rest position, 'position 1', against a cam part of yoke 12 which has a lower cam 53 and which is resilient and profiled in a direction orthogonal to that as viewed, as being convex. When that yoke 12 is actuated and pulled down for charging the cup 15 with the desired dosage of medicament, the part 110 rides up ramp 106

of the cam, shown in 'position 2', and then, to effect transfer, it moves gently and smoothly upwardly along a ramp 112 to the inhalation position at 'position3'. On return of the yoke 12 upwardly, arrow Y, the part 110 of the device 4 returns along the ramp 112 of the cam shown in 'position 4', thereby returning the device 4 to the position for charging.

[0073] This action is exemplified in Fig. 11 where the lower end of the yoke 12, adjacent the mouthpiece, follows a single cam follower 56 of a cam which is rotatable by the mouthpiece 6, or cover 52 (Fig. 9).

[0074] Fig. 12 shows a breath actuated dry powder inhalation apparatus 57 in which there is a force handling unit 58 on top of a lower body part 59 of the apparatus 57, the device 4 being actuatable only when the patient takes a breath as known from previous breath operated examples such as that marketed under the trade mark Easi-Breathe. In this embodiment when the patient inhales a mechanism 60 shown in Fig. 13 is operative to provide for dispensation of the required dose of medicament. In this embodiment, between the upper 61 and lower 62 flanges of the reservoir 2, there is a double cam or gear arrangement, the first or upper 63 one of which as viewed has an extension 64 which engages the device 4 to hold it in the charging position, there being an elongate actuating member 65 which is operative to rotate the cam or gear 67 whereby it in turn can rotate the cam or gear 63 out of contact with the device 4 thereby allowing the device 4 to move for inhalation.

[0075] The elongate member 65 is mounted under pressure of a spring 66 there being a valve and seal arrangement 68 operable when a patient breathes on the mouthpiece to lift a flap valve 69 thereof, thereby allowing atmospheric air to enter a space 70 defined between the upper and lower flanges 61, 62 of the reservoir and between a wall 71 spacing those two flanges apart so that the spring 66, under the pressure of which the elongate member is mounted, is retracted thereby, the air pressure either side of the wall being equalised.

[0076] Turning now to Fig. 14, this shows schematically the device 4 mounted underneath the charging opening 4' from the reservoir 2 so that the cup 15 is aligned with that charging opening. The device 4 is mounted under pressure of a spring to return to the position shown, there is also a damper device 72 such as a dash pot which on operation of the mechanism to move the device longitudinally bodily to the left as shown by the arrow 'R', is active to provide a smooth, controlled passage from the charging opening to the air channel, for inhalation of the desired predetermined dose of powdered medicament.

[0077] All the embodiments herein described with reference to the accompanying drawings describe dry powder inhalation apparatus which provides for charging of a cup of a discharge device without compaction and for smooth and controlled transfer of the device to air channels thereby avoiding compaction, and or spillage, so that on repeated operation, the desired metered dose will be dispensed each time a patient uses the apparatus.

[0078] It will be understood that the controlled smooth movement of the embodiments of the invention described herein does not affect individual doses dispensed when a patient uses the apparatus on inhalation. The apparatus seeks to prevent inadvertent multiple dosing as a result of multiple actuations before use by a patient. In this preferred embodiment, (Fig. 15), the controlled smooth movement changes the method by which the prior art slide carrier is transferred to the inhalation position. Instead of suddenly releasing the slide carrier as the yoke lower descends, the trigger component for the second zone has a sloped portion instead of the ledge in the second zone of the prior mechanism. The first zone remains the same as the previous design, a sudden drop generates the metering pulse from the bellows.

[0079] As the yoke lower reached the second zone the movement is controlled by the opening of the mouthpiece cover. The yoke lower ledge has also been replaced by a slope. This controls the position of the slide carrier. The slide carrier position during transfer is now linked to the mouthpiece cover. Instead of the sudden stop against the hopper upper part, the slide carrier is gradually allowed to transfer across to the inhalation position, and the stopping is more controlled, and very smooth.

[0080] As a result of the smooth transfer, there is no jolting of the powder, and only a very small amount, if any, is spilled. A single actuation results in the same pharmaceutical performance as the prior mechanism, the difference is apparent for multiple actuations.

What is claim is:

1. A dry powder inhalation apparatus, comprising a reservoir for medicament, a mouthpiece for insertion in the mouth of a user for inhalation of a predetermined dose of medicament, a delivery channel between a discharge outlet of the reservoir and the mouthpiece for delivering said predetermined dose of medicament, a device normally held adjacent the reservoir for receiving said predetermined dose of medicament from said discharge outlet and transferring it to the delivery channel, and a mechanism adapted to release the device and permit controlled movement thereof to the delivery channel for said delivery.
2. The apparatus of claim 1, further comprising a cup for receiving the said dose and a longitudinally slidable body mounting said cup, the mechanism comprising abutment means which is movable to release the device for movement to the delivery channel.
3. The apparatus of claim 2, further comprising the abutment means being bodily movable by an actuation means.
4. The apparatus of claim 3, comprising a yoke member which is shiftable bodily towards and away from the mouthpiece, and mounting limbs one of which has a cam follower for following a cam which is rotatable for actuation of the yoke member which carries the actuation means in the form of a ramp up which a part at least of the device can travel for controlled movement thereof towards the delivery channel.
5. The apparatus of claim 4, the actuation means comprising an element for returning the device to the discharge outlet.
6. The apparatus of claim 5, the element comprising an inclined ledge down which the part travels to said charging position.
7. The apparatus of claim 6, wherein the yoke member comprises a lower (in use) cam which is resilient and has a surface profile.
8. The apparatus of claim 7, wherein the surface profile is convex in configuration.

9. The apparatus of claim 8, wherein the lower in use end of the yoke is adjacent the mouthpiece.
10. The apparatus according to any preceding claim, wherein the abutment means comprises a resilient member which is flexible out of the path of the device.
11. The apparatus of claim 10, wherein the resilient member comprises a one piece member of substantially J- or U-configuration one limb of which is movable for releasing the device.
12. The apparatus of claim 11, wherein the movable limb has a finger-operable tab projecting from a housing of the apparatus.
13. The apparatus of claim 12, wherein the tab has indicia indicating the direction of flexing of the limb for release of the device.
14. The apparatus of claim 3, wherein the actuation means comprises a resiliently mountable slidable member which has a tab projecting through a bore of a body of the apparatus for releasing the device.
15. The apparatus of claim 14, wherein the slidable member having indicia which can be read through the bore for indicating the position of the device.
16. The apparatus of claim 15, wherein the indicia comprises a colour code indicia.
17. The apparatus of claim 3, wherein the actuation means comprises a resiliently and pivotably mounted detent means which is shiftable bodily about its pivot axis to release the device.
18. The apparatus of claim 17, wherein the detent means has a finger grippable projection which projects there from and through a slot in the body of the apparatus for bodily shifting of the detent when the projection is moved along the slot.
19. The apparatus of claim 3, wherein the actuating means comprises a resiliently mounted plunger means which has one end projecting through a bore in a body of the device and an opposite end adapted to engage the device for shifting same bodily to said delivery channel.
20. The apparatus of claim 19, wherein the plunger means has a substantially cylindrical body member connecting the one end and the opposite end, the opposite end being enlarged relative to the body member.

21. The apparatus of claim 20, wherein there is a relatively soft cushion member of the opposite end for contacting the device.
22. The apparatus of claim 3, wherein the actuation means comprises an electrical, electronic or electro-mechanical means.
23. The apparatus of claim 22, wherein the actuation means comprises a solenoid means actuated by a switch device for actuation of the device.
24. The apparatus of claim 23, wherein the switch device is operable manually by a user.
25. The apparatus of claim 23, wherein the switch device is operable by inhalation of a breath by a user.
26. The apparatus according to any of Claims 22 to 25, further comprising a power source for the electrical, electronic or electro-mechanical means.
27. The apparatus according to any preceding claim, further comprising a cover for an end of the discharge channel at the mouthpiece, the cover being movable between a position covering the discharge channel and a position for discharging said dose, whereby to allow actuation of the mechanism.
28. The apparatus of claim 27, wherein the cover comprises a relatively rigid disc carried by opposed arms which at an end thereof opposite the disc mount a cam which has a profile for allowing movement of a cam follower in a direction away from the device whereby to allow operation of the actuation means for bodily movement of the abutment means.
29. The apparatus of claim 28, wherein the disc in its first mentioned position is housed within a guard of the apparatus, which guard is pivotably mounted for access to the disc.
30. The apparatus of claim 3, further comprising a breath actuable apparatus.
31. The apparatus of claim 30, wherein the mechanism is between opposed spaced walls of the reservoir and has a member which is retractable on a user taking a breath on the mouthpiece.
32. The apparatus of claim 31, wherein the mechanism comprises cooperating rotatable means one of which has a detent for engaging the device and the other of which is

operable to maintain the detent in engagement with the device and to allow rotation of the one means to release the detent and device.

33. The apparatus of claim 32, wherein the mechanism further comprises a stop member retractable as a user takes a breath on the mouthpiece, and adapted to release the other rotatable means and the detent.
34. The apparatus of claim 33, wherein the rotatable means comprises cam or gear means.
35. The apparatus of claim 33 or 34, wherein the stop member comprises an elongate mounted member which is biased to engage the other rotatable means and a flap valve which is operable to allow air into a space between said opposed walls to equalise air pressure inside and outside the space and bias the elongate member to operate the cam or gear means.
36. The apparatus according to any preceding claim, wherein the device is mounted under pressure resilient means.
37. The apparatus of claim 36, wherein the pressure resilient means comprises spring means.
38. The apparatus according to any preceding claim, comprising a damper means for damping movement of the device.

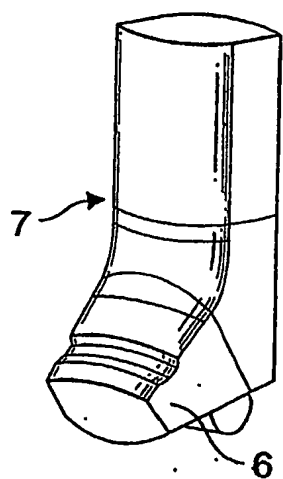


FIG. 1

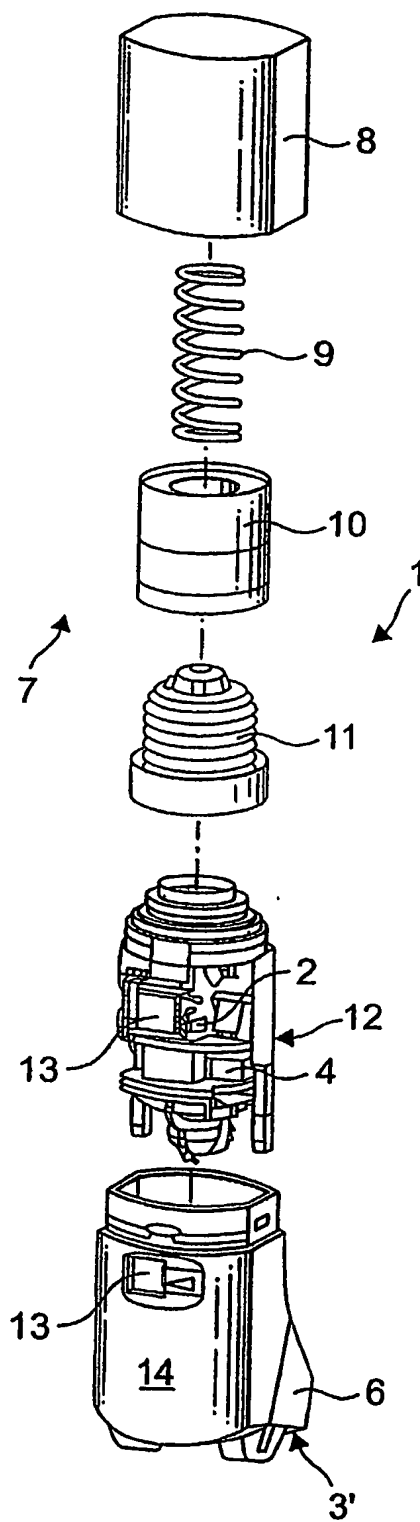


FIG. 2

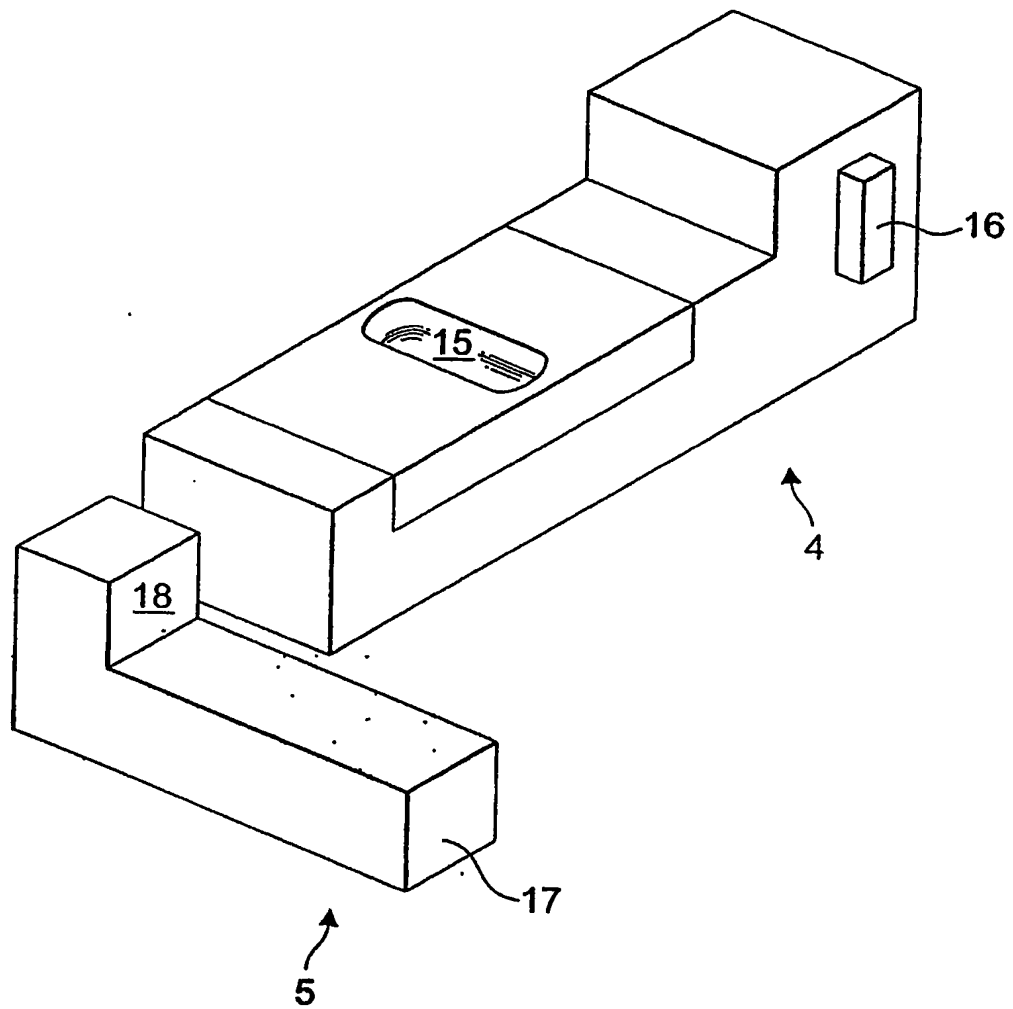


FIG. 3

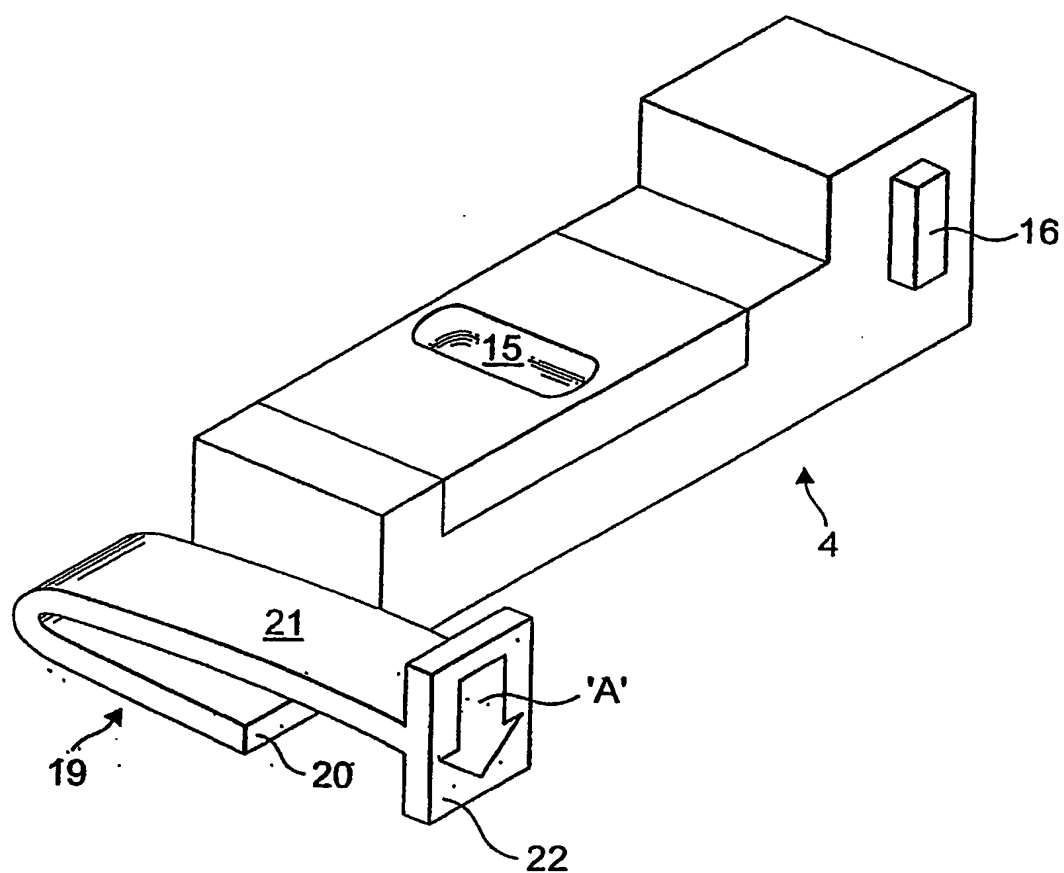


FIG. 4

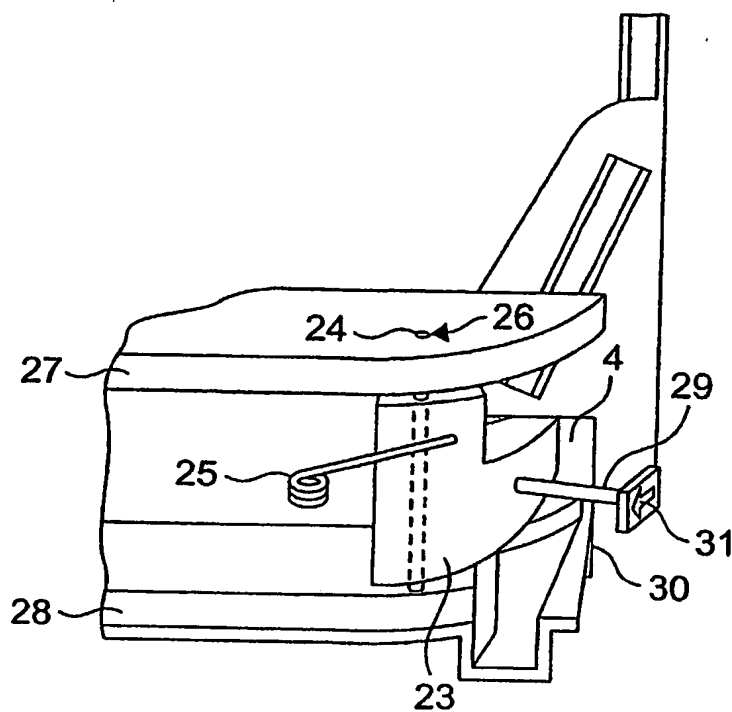


FIG. 5A

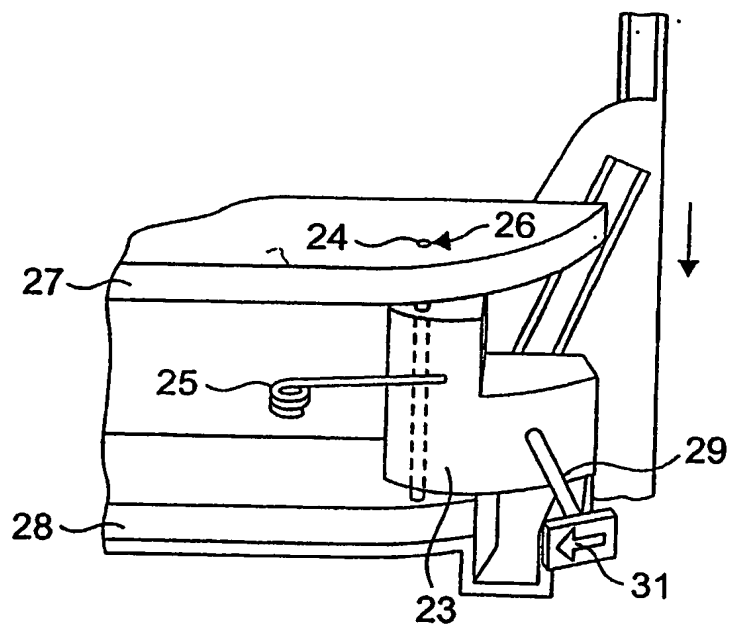


FIG. 5B

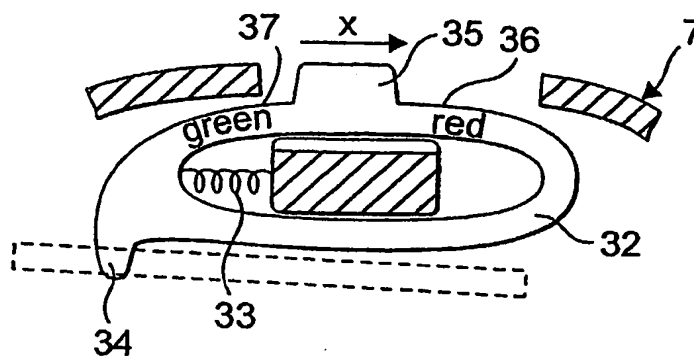


FIG. 6

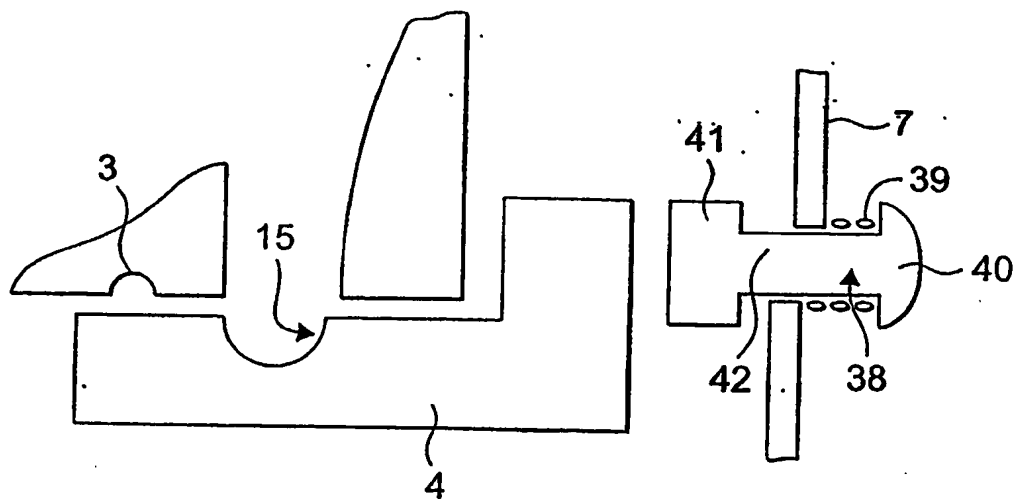


FIG. 7

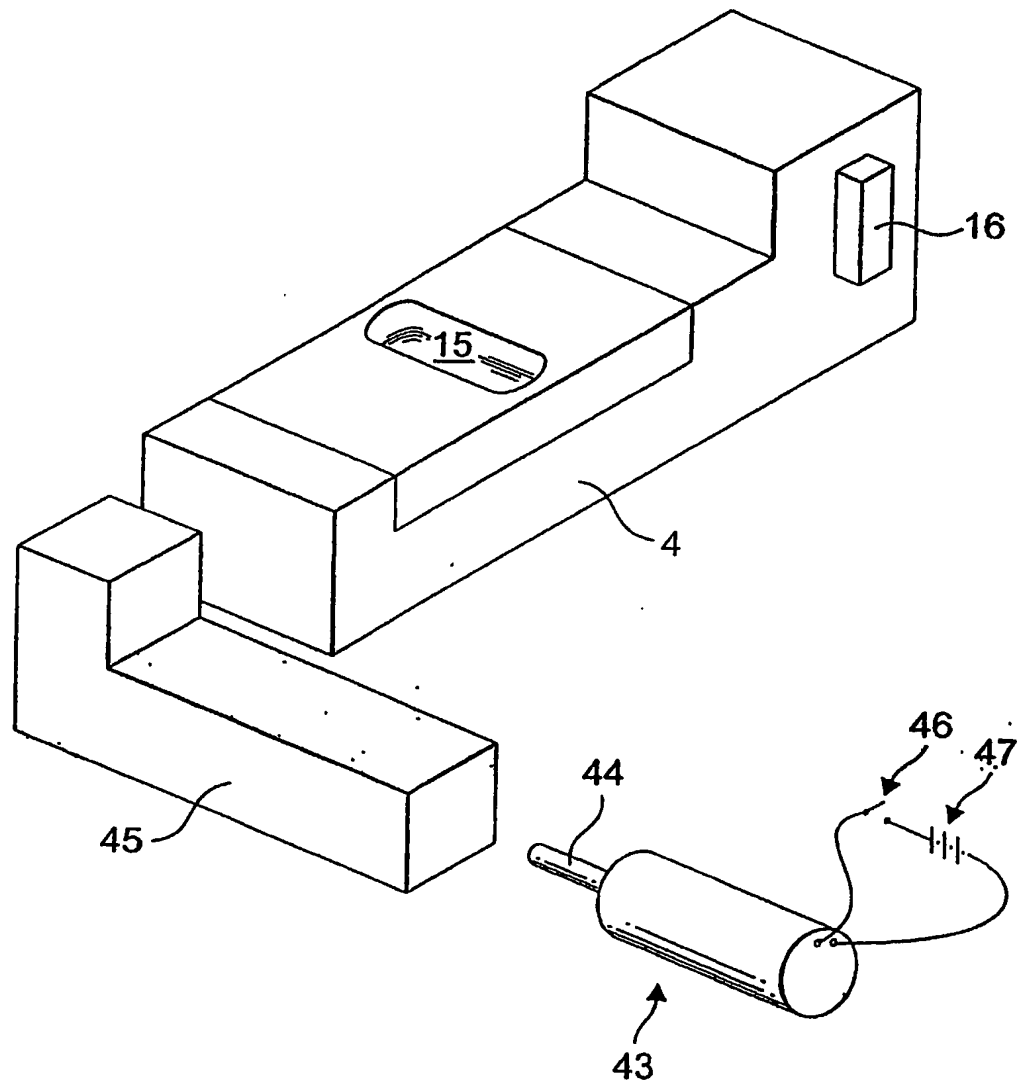


FIG. 8

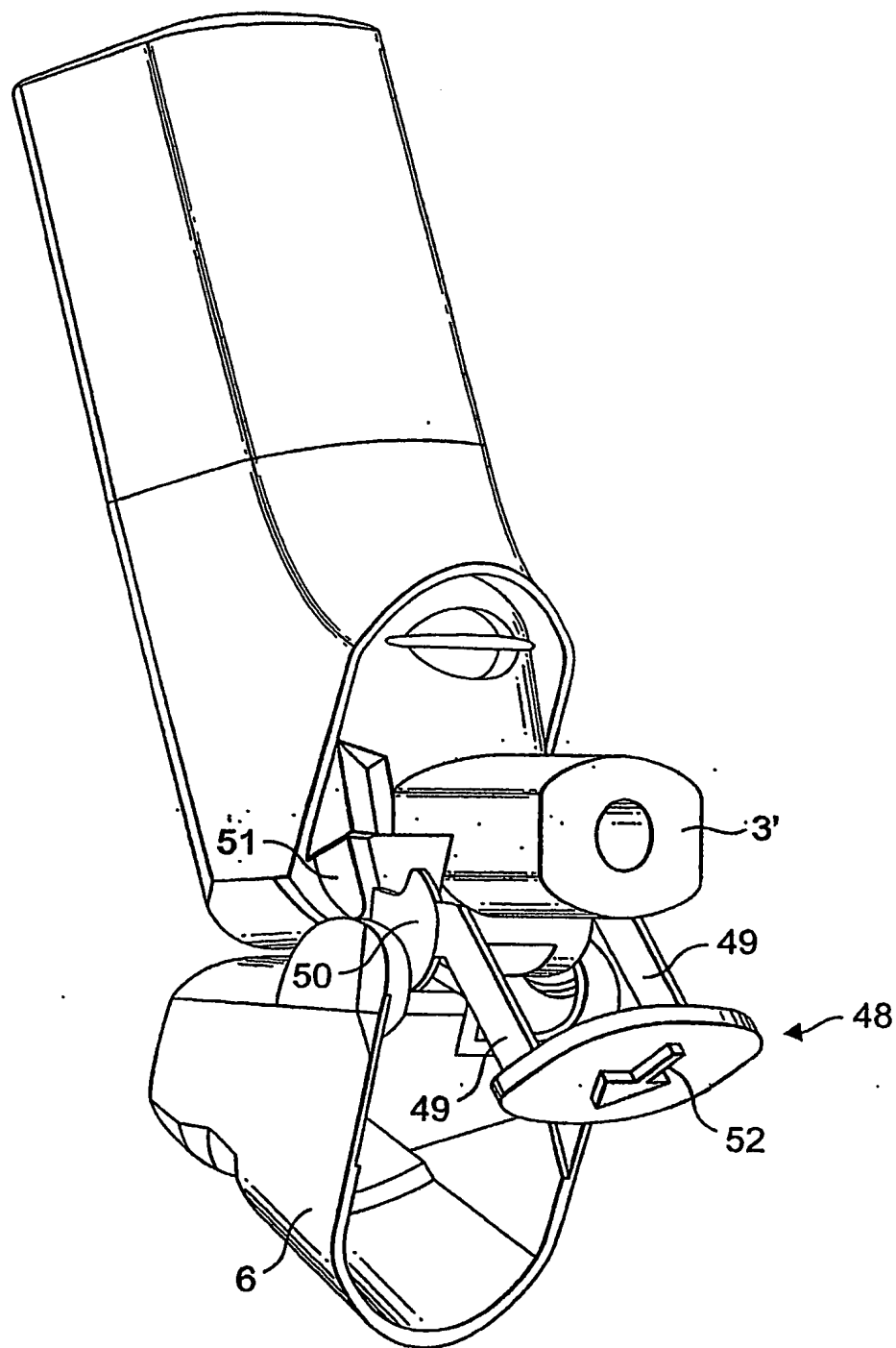


FIG. 9

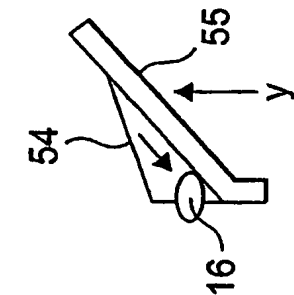


FIG. 10D

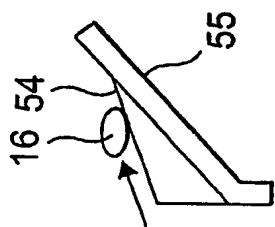


FIG. 10C

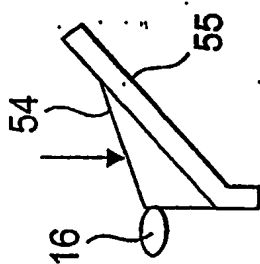


FIG. 10B

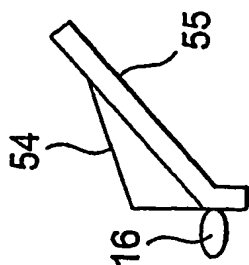


FIG. 10A

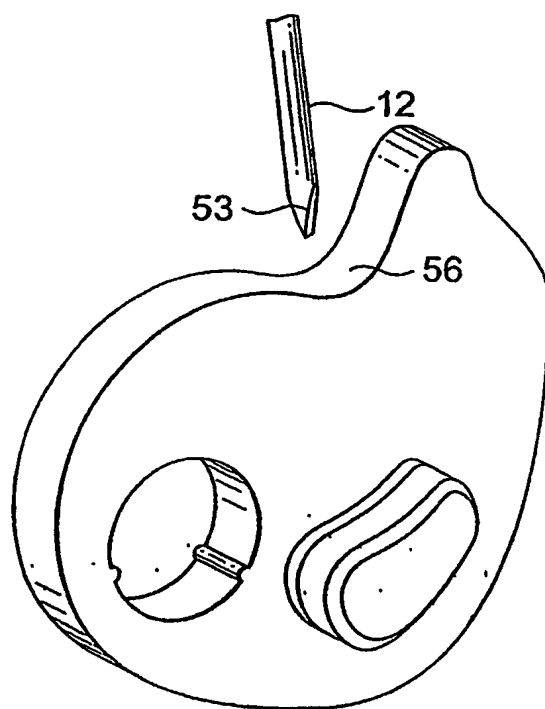


FIG. 11

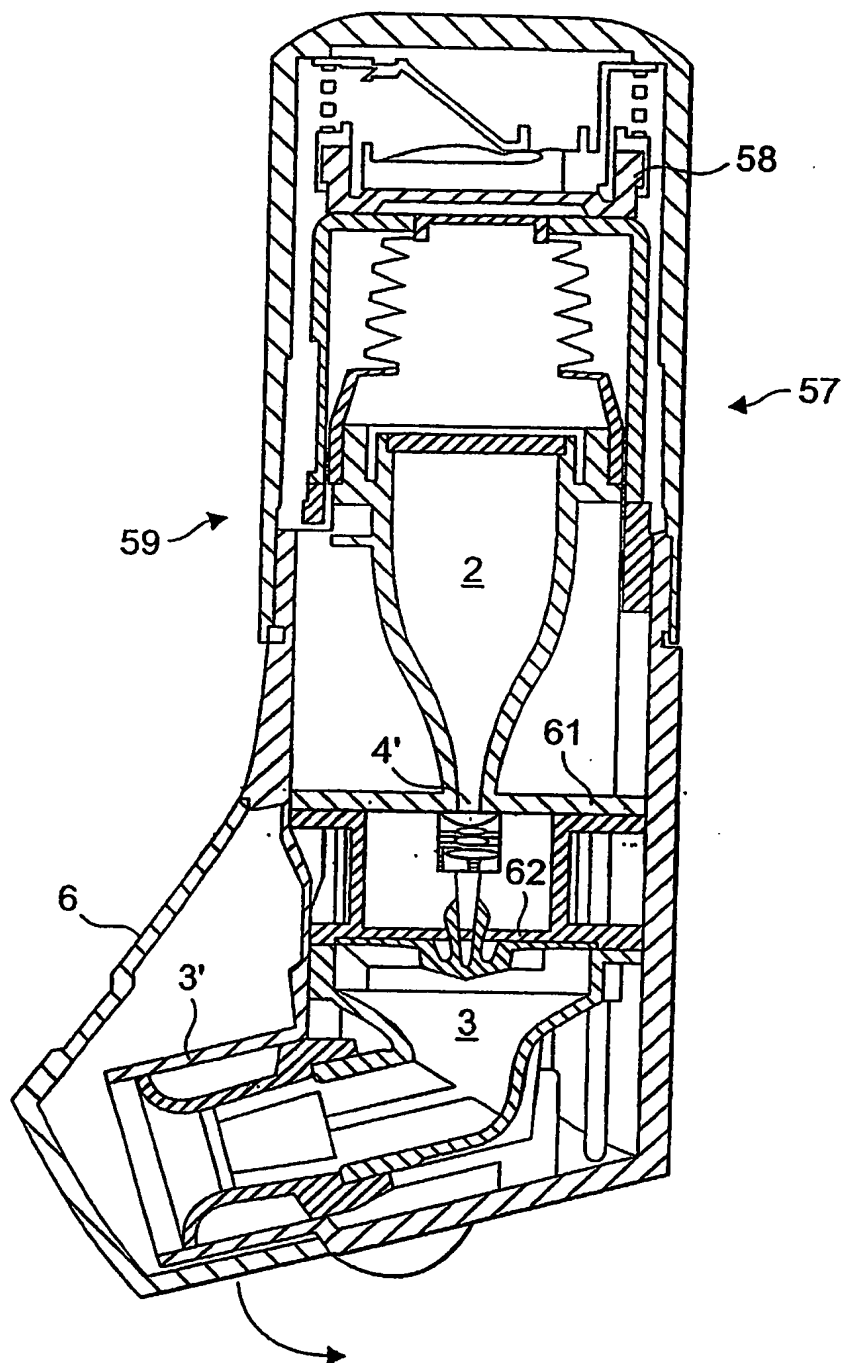


FIG. 12

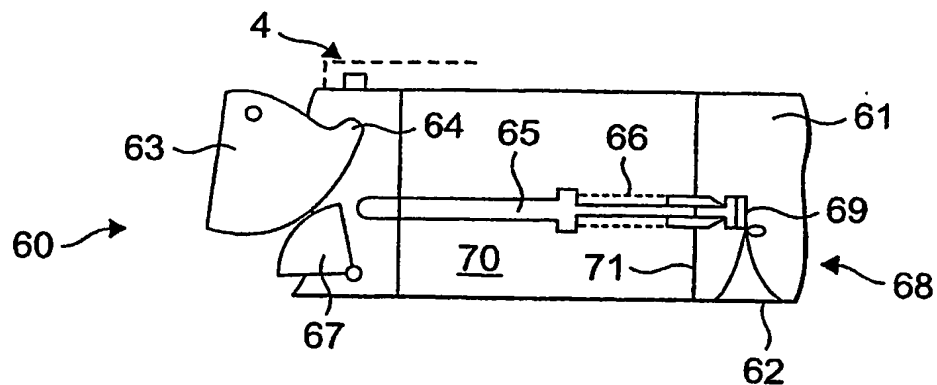


FIG. 13

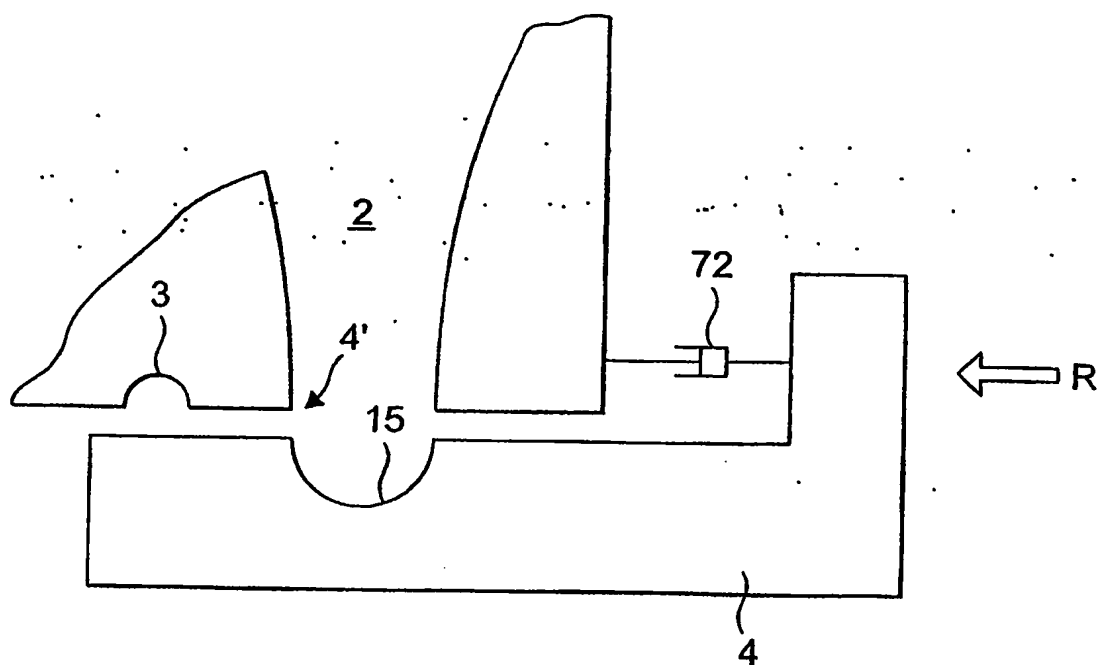


FIG. 14

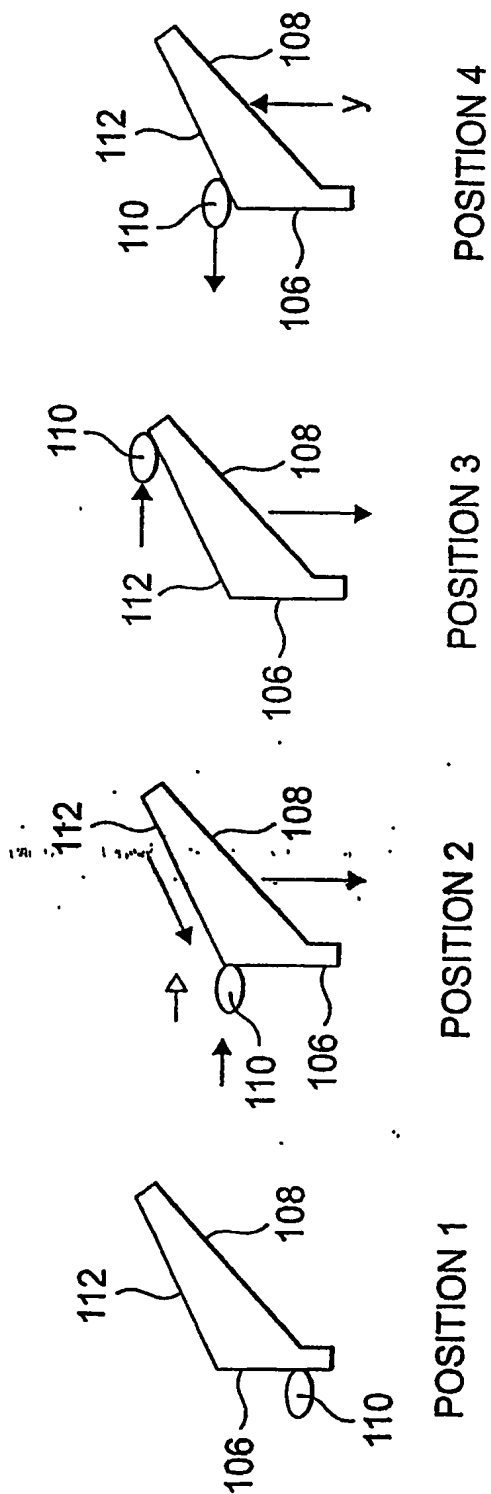


FIG. 15

TEVA 3.3-001

LD-515\

IN THE MATTER of United States Patent Application Number 10/574,386

EXHIBIT SR2 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY



SAMANTHA CLAIRE RADLEY



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IN THE MATTER of United States Patent Application Number 10/574,386

EXHIBIT SR3 TO THE
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Subsidiary of **IVAX** Corporation

Ms Rachel Streibig
Flat 4 Cyna Court, Cambridge Road
London
E11 2PW

Albert Basin, Royal Docks
London E16 2QJ

Telephone 08705 02 03 04
Fax 08705 32 33 34

2nd November 2006

Dear Rachel,

RE: US National Phase of PCT/US2004/0032160 for
DRY POWDER INHALATION APPARATUS
in the name of Norton Healthcare Limited – Our Ref: NHC0083US

Please find enclosed a declaration for use in the prosecution of the above patent application in the United States by Norton Healthcare Limited. Please can you sign and date the declaration where indicated. The Declaration is required so that you are formally recognised by the USPTO as an inventor for this patent application.

There is also an Assignment form that should be witnessed by someone who knows you at the time of your signing. Please can you sign the assignment in the presence of such a witness who should then also sign the assignment to show that your signature is indeed your true signature. Again, this assignment is merely a formality that is required by the USPTO to confirm that as an employee of Norton Healthcare Ltd, you assigned your rights in the invention to Norton Healthcare Ltd. In English law, an employee automatically assigns their rights in an invention to their employer.

This declaration and assignment only relate to this patent application. Consequently, if you are named as an inventor on other applications, we will have to contact you again to request your signature. Thank you for your cooperation.

Please endeavour to return the signed forms in the stamped, addressed envelope provided by 17th November 2006. Unfortunately, the USPTO set a time limit to file these documents and if we do not meet the date, fines are incurred.

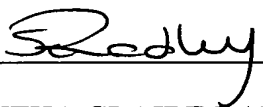
If you have any queries, please do not hesitate to contact the Patent Department.

Yours sincerely

David W. Cottam Ph.D.
Intellectual Property Counsel
Norton Healthcare Limited

IN THE MATTER of United States Patent Application Number 10/574,386

EXHIBIT SR4 TO THE
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Times given are local to the service area in which the shipment checkpoint is recorded.

Air Waybill Number	Origin Service Area	Destination Service Area	Status
9969165043	Docklands - UK	Docklands - UK	Awaiting pick up by r as of: April 03, 2007



9969165043 - Detailed Report

Date	Time	Location Service Area	Checkpoint Details
January 08, 2007	13:17	Docklands - UK	Shipment picked up
January 08, 2007	17:31	Docklands - UK	Departing origin
January 08, 2007	19:55	Docklands - UK	Departed from DHL facility i
January 09, 2007	05:17	London-Heathrow - UK	Departed from DHL facility i UK
January 09, 2007	06:49	Docklands - UK	Arrived at DHL Facility
January 09, 2007	08:52	Docklands - UK	With delivery courier
January 09, 2007	12:04	Docklands - UK	Delivery attempted; recipier
January 10, 2007	08:30	Docklands - UK	Shipment on hold
January 11, 2007	08:05	Docklands - UK	Shipment on hold
January 12, 2007	07:57	Docklands - UK	Shipment on hold
January 15, 2007	07:54	Docklands - UK	Shipment on hold
January 17, 2007	17:06	Docklands - UK	Shipment on hold
January 18, 2007	09:12	Docklands - UK	With delivery courier
January 18, 2007	11:06	Docklands - UK	Delivery attempted; recipier
January 19, 2007	08:52	Docklands - UK	Shipment on hold

January 22, 2007	08:27	Docklands - UK	Shipment on hold
January 23, 2007	08:18	Docklands - UK	Shipment on hold
January 24, 2007	08:59	Docklands - UK	Shipment on hold
January 25, 2007	08:00	Docklands - UK	Shipment on hold
January 31, 2007	14:01	Docklands - UK	Awaiting pick up by recipient
February 01, 2007	11:18	Docklands - UK	Awaiting pick up by recipient
February 02, 2007	11:19	Docklands - UK	Awaiting pick up by recipient
February 05, 2007	12:26	Docklands - UK	Awaiting pick up by recipient
February 06, 2007	11:13	Docklands - UK	Awaiting pick up by recipient
February 08, 2007	11:29	Docklands - UK	Awaiting pick up by recipient
February 09, 2007	10:51	Docklands - UK	Awaiting pick up by recipient
February 14, 2007	10:30	Docklands - UK	Awaiting pick up by recipient
February 16, 2007	12:34	Docklands - UK	Awaiting pick up by recipient
February 20, 2007	17:06	Docklands - UK	Awaiting pick up by recipient
February 27, 2007	09:59	Docklands - UK	Awaiting pick up by recipient
March 05, 2007	10:53	Docklands - UK	Awaiting pick up by recipient
March 08, 2007	10:29	Docklands - UK	Awaiting pick up by recipient
March 12, 2007	14:17	Docklands - UK	Awaiting pick up by recipient
March 15, 2007	10:24	Docklands - UK	Awaiting pick up by recipient
March 19, 2007	11:45	Docklands - UK	Awaiting pick up by recipient
March 20, 2007	11:58	Docklands - UK	Awaiting pick up by recipient
March 22, 2007	10:38	Docklands - UK	Awaiting pick up by recipient
March 23, 2007	09:10	Docklands - UK	Awaiting pick up by recipient
March 27, 2007	11:29	Docklands - UK	Awaiting pick up by recipient
March 29, 2007	11:46	Docklands - UK	Awaiting pick up by recipient
March 30, 2007	09:37	Docklands - UK	Awaiting pick up by recipient
April 02, 2007	11:40	Docklands - UK	Awaiting pick up by recipient
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